The impact of hearing impairment and the provision of hearing aids on poverty, mental health, quality of life and activity participation in Guatemala

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Statement of Own Work

I, Mark James Spreckley confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Abstract

The World Health Organisation estimates that 466 million people worldwide have disabling hearing loss and 80% of those affected are living in low and middle income countries.

Data on the impact of hearing loss or hearing aid provision in low and middle income countries is lacking. The purpose of this research project was to address the evidence gap and assess the multi-dimensional impact of hearing impairment and the provision of hearing aids on poverty, mental health, quality of life and activity participation of adults living in Guatemala.

In this non-randomised controlled study 180 adult cases with an audio-metrically assessed, bilateral, disabling hearing impairment of moderate to profound severity were compared with 143 age and sex matched control participants with confirmed 'normal' hearing or mild, non-disabling hearing loss. All cases and controls were interviewed using a structured questionnaire. Case participants were then assessed and fitted with hearing aids. After a mean period of 7.5 months, cases and controls were re-interviewed to assess the impact of this intervention. Twenty-two in-depth interviews complemented the quantitative research.

At baseline, individual earnings were 43% significantly lower among the cases than the control group. Total monthly household expenditure and per capita expenditure were significantly higher (p value = 0.001) in controls ($611, $203) as compared with cases. There was a positive association between hearing loss and the experience of depressive symptoms, but not depression. Cases were identified as having a poorer quality of life across a range of domains.

At follow-up, the majority (71%) of cases reported that they used their hearing aids on a daily basis. There was no significant change in employment status for both case and control groups. Household income increased among the cases between baseline and follow-up, but not among the controls. There was no significant change to case participant's per capita expenditure at household or

individual level. In contrast, for the control group there was a significant decline in the level of both household and individual per capita expenditure.
There was a reduction in depression and its related symptoms and severity as well as a significant improvement in the quality of life of cases across all domains, except for social relationships. A high level of satisfaction with hearing aid use was reported globally and across a range of constituent satisfaction with amplification in daily life scores. These quantitative findings were broadly supported by the qualitative data.

The research has demonstrated the positive impact that hearing aids, as part of a comprehensive fitting and aural aftercare programme may have on significantly improving quality of life and reducing symptoms of depression for people living in Guatemala. Some of the key barriers and challenges to intervention include lack of ear and hearing health awareness, stigma, financial cost and audiology clinic accessibility. The outcomes of this research have implications for ministerial advocacy, aural rehabilitation programme development and community outreach expansion.

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Figures & Tables

Acronyms and Abbreviations

Community Health Workers	CHWs
Confidence Level	CL
Doctor of Public Health	DrPH
Disability-adjusted Life Year	DALY
Disabling Hearing Loss	DHL
Ear, Nose and Throat	ENT
Global Burden of Disease	GBD
Gross Domestic Product	GDP
International Classification of Functioning and Disability	ICF
London School of Hygiene and Tropical Medicine	LSHTM
Low and Middle Income Countries	LMIC's
Noise Induced Hearing Loss	NIHL
Non-Government Organisation	NGO
Odds Ratio	OR
Per Capita Expenditure	PCE
Quality of Life	QoL
Randomised Controlled Trial	RCT
Social Representation Theory	SRT
Standard Deviation	SD
Theory of Change	ToC
United Kingdom	UK
World Health Organisation	WHO

1. Introduction

1.1 Thesis Framework

The specific purpose of this research project is to address the evidence gap relating to the impact of hearing loss and the potential benefits of hearing aids in Guatemala, and this question is explored throughout this thesis.
This thesis is comprised of four sequential chapters commencing with an introduction. This introductory chapter defines the research framework and explores the current body of knowledge. It provides a definition and classification of hearing loss, describes the anatomy and physiology of the auditory system, discusses the prevalence and causes of hearing loss, and proposes a conceptual framework from which the impact of hearing loss is reviewed. The concept of audiological rehabilitation is discussed, concluding with a rationale for the current study and establishing of a core set of research objectives.

The methodology chapter presents a 'Theory of Change' model to describe the research project design and the relationship between baseline state, intervention and outcome. The chapter provides a systematic and detailed account of how the study was planned and implemented. It describes the project organisation, case and control selection, qualitative and quantitative data collection, implementation processes and data analysis.

In the results section, the quantitative results provide a numerical account of research participation, the characteristics of cases and controls at baseline and follow-up and explores the impact of intervention. The quantitative data is presented as a series of tables, descriptive charts and explanatory text. The qualitative results are presented separately, as an in-depth exploration of the functional impact of hearing loss and hearing aid usage and experience. The analysis is presented as a series of illustrative quotes and explanatory text, enabling these findings to be compared with the quantitative analysis. In the final section, two case studies are presented, and the personal experience of the researcher is explored with respect to how it may impact on the study results.

The discussion chapter summarises the key findings of the study in the context of previous literature. The wider implications, recommendations and areas for further study are proposed. The initial section of the discussion reviews the key results of the study, examining the existing literature and comparing the qualitative findings with the outcome of the quantitative results. The strengths and limitations of the research are explored. Recommendations for advocacy, policy development, service provision and further research are proposed based upon the barriers and facilitating factors to intervention. In the concluding section a reflective, personal account of the student's journey as a Doctor of Public Health Candidate is presented.

1.2 Hearing

> 'The sense of hearing serves to integrate individuals with their environment through the perception of normal, everyday sounds that characterise our environment and lets us feel connected to our world.' [86]

The interaction between a person and their surrounding environment is mediated through sensory experiences. The sense of hearing facilitates communication and fosters social interaction.[1] Effective communication is the transfer of information, meaning or intent between two or more people and involves both activity and participation.[2] To communicate an individual accesses acoustic information, (hearing), employs attention and intention (listening), correctly interprets the acoustic and linguistic information (comprehension) and uses and transmits this information effectively.[3] Hearing loss is a health condition that affects the anatomical and physiological parts of the auditory system. It is the most common form of human sensory deficit.[4]

1.3 Ear Structure & Function

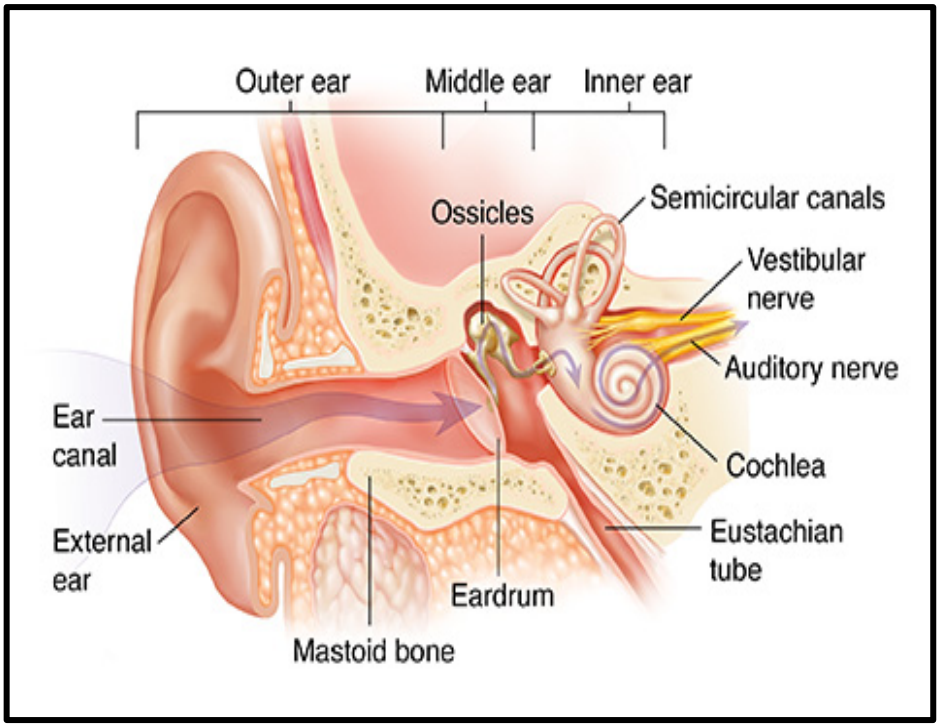
The ear is a complex, paired organ that has dual responsibility for hearing and balance.[5] The auditory system is comprised of three distinct components: the outer, middle, and inner ears. The external ear consists of the auricle or pinna and the ear canal, the middle ear includes the tympanic membrane and the ossicular chain. The inner ear comprises of the cochlea. This auditory system is illustrated in Figure 1.

The function of the ear is to analyse environmental sounds, converting physical vibration into an encoded nervous impulse which is transmitted to the brain where the central auditory pathways process the information and provide interpretation.[6,7] The outer-ear receives sound waves from the environment which the auricle captures and directs into the external auditory canal. Increases and decreases in sound-induced air pressure, vibrate the tympanic membrane resulting in a mechanical response. Inside the middle ear, three ossicles, the malleus, incus, and stapes form a chain and conduct sound vibrations from the air-filled outer-ear to the fluid filled inner-ear.
The cyclic motion created by the stapes bone displaces a liquid mass in the inner ear, which results in a traveling oscillating wave along the basilar membrane of the cochlea.[8]

The cochlea houses a sophisticated machinery responsible for the detection of sounds and the conversion from mechanical energy intro electrical potentials. The Organ of Corti is the sensory epithelium within the cochlea where hair cells, supporting cells and nerve fibres interact to make hearing happen.[9]
There are two types of mechano-sensory cells: inner and outer hair cells. They both transduce mechanical force generated by sound waves into electrical signals. Inner hair cells are responsible for detecting sounds from the acoustic environment and transmitting the information to the brain and the outer hair cells are responsible for the active mechanical amplification process that leads to the fine tuning and high sensitivity of the inner ear.[10]

The eighth cranial nerve, also known as the vestibulocochlear nerve is made up of two distinct fibre bundles, the cochlear and vestibular nerves. Each nerve has its own specific function, peripheral receptors and central neural pathways and endpoints within the brain.[11] The cochlear nerve is primarily responsible for transmitting the electrical impulses generated for hearing and localization of sound and the vestibular nerve is responsible for carrying impulses involved in maintaining balance and equilibrium.[12]

Figure 1: Anatomy of the Ear[13]



1.4 Hearing Loss and its Classification

Hearing loss is a diminished ability to detect and localise sounds and recognize speech which may adversely affect the ability to communicate.[14] Hearing impairment is a broad term that refers to hearing losses of varying degrees, ranging from mild to profound.[15] Hearing loss may be classified based on a broad range of distinctions such as, anatomical, pathological, severity-based, functional or age-specific.[16]

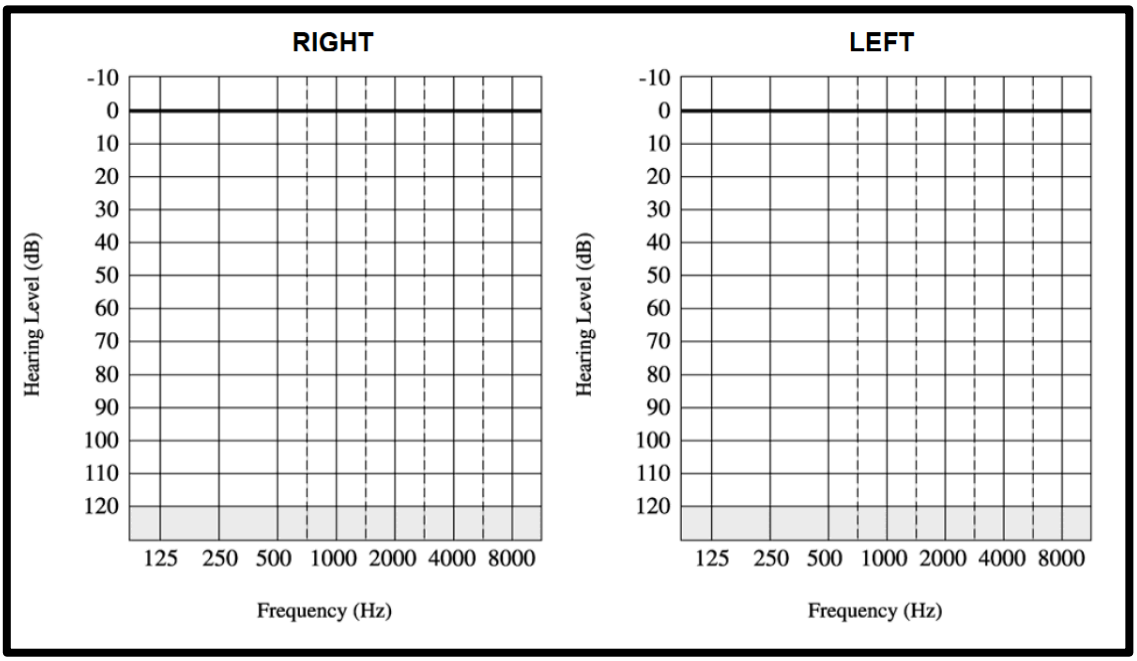
When describing hearing impairment three attributes are considered, the type of hearing loss or part of the hearing mechanism that is affected, the degree of hearing loss, the range and volume of sounds that are not heard and the configuration, and the range of pitches or frequencies at which the loss has occurred.[15] A hearing loss may also be labelled as unilateral or bilateral, depending on whether the loss is in one (unilateral) or both (bilateral) ears. The degree of loss might be the same in both ears, symmetrical hearing loss or it could be different for each ear, asymmetrical hearing loss.[15]

Classification of hearing loss is an essential component of audiological assessment and classifying hearing loss according to the type, degree and configuration is the primary information required to determine further test procedures and to direct medical and/or audiological interventions. The main clinical classification of hearing loss is based on the severity of hearing impairment, as assessed by pure-tone audiometry.[17]

1.5 Pure-Tone Audiometry

A sound is characterized by its frequency and intensity. The frequency or pitch of a sound is measured by counting the number of cycles per second in the vibration (Hz) and the intensity of a sound is a measure of loudness.[6] Hearing is assessed by listening to different pure-tone signals through a pair of headphones and recording air conduction. Hearing loss is determined by measuring the softest level of sound that an individual can detect across a range of frequencies.[18]
This audiometric threshold is recorded on a graph known as an audiogram. As shown in Figure 2, the audiogram presents the sound frequency, (pitch) ranging from low to high frequency on the horizontal axis which is measured in hertz (Hz) and sound intensity or volume (Hearing Level) which is measured in decibels (dB) on the vertical axis.[8]

Figure 2: Audiogram[19]



Adults and children with thresholds between 0 and 25 dB, across all frequencies are considered to have 'normal' hearing.[20] The World Health Organisation has identified grades of hearing loss (Table 3) and defines 'Disabling Hearing Loss' as 41dB or greater in the better hearing ear in adults (15 years or older) and 31dB or greater in the better hearing ear in children (0 to 14 years).[1,21]

Historically, prevalence studies have measured hearing loss using different definitions and frequency thresholds, including measurements of the better or worse ear or a specific age group.[22] Hence, there is a diversity of definitions of hearing impairment and comparison among studies is difficult.[23]

It is also acknowledged that the numerical definition of hearing loss is a limited measure of the impairment and the production and interpretation of a pure tone audiogram is not an effective measure for recognising the practical challenges of disabling hearing loss and the difficulties and compensatory measures that people may experience in their daily lives.[24] As such, two people with the same

[1] Based on pure tone average of thresholds at 0.5, 1, 2, 4 KHz in the better ear.

level of hearing loss may experience different impacts on their ability to communicate and to participate in everyday life.

Table 3: WHO Grades of Hearing Impairment

Grade (0-4)	Measure (dB)	Interpretation	
0 (None)	25 dB or less	No or slight problem Hears whispers	
1 (Slight/Mild)	26-40 dB	Hears & repeats words in normal voice at one metre	
2 (Moderate)	Child: 31-60 dB Adult: 41-60 dB	Hears & repeats words in raised voice at 1 metre	**Disabling Hearing Impairment**
3 (Severe)	61-80 dB	Hears words shouted into better ear	
4 (Profound)	81 dB or more	Cannot hear/understand shouted voice	

Based on pure tone average of thresholds at 0.5, 1, 2, 4 KHz in the better ear

1.6 Causes of Hearing Loss

Hearing loss is a symptom of many different diseases that affect the organs of hearing and a hearing impairment may be caused by a range of congenital or acquired health conditions.[16] Congenital hearing loss means that hearing loss is present at or around the time of birth, whereas acquired causes may lead to hearing loss at any age.[1]

The acquired causes of hearing loss may include:[25]

- Infectious diseases such as meningitis, measles and mumps
- Chronic ear infections
- Medications used in the treatment of neonatal infections, malaria, drug-resistant tuberculosis and cancers
- Injury or trauma to the head or ear
- Excessive noise, including occupational or recreational exposure
- Ageing and physiological degeneration
- Wax or foreign bodies which may block the ear canal
- Genetic factors

Dependant on when the hearing loss is acquired and its severity, people may exhibit characteristic signs and behaviours such as repeatedly questioning elements of a conversation that have not been heard, providing inappropriate answers to misheard questions and the use of an excessively loud speaking voice.[16] They often employ compensatory measures such as turning up the volume of the radio or television or by turning the 'better' ear to the sound source. Vision may be used as an additional aid to speech recognition, with a compensatory reliance on lip-reading.

Congenital hearing loss can be caused by genetic or non-genetic (acquired) factors.[23] It is estimated that deafness occurs in 1:1000 neonates and the cause is genetic, due to a gene mutation in about 50% of all cases.[26] A positive family history can be instrumental in the diagnosis of hereditary hearing loss.[27]
Non-genetic factors are linked to pregnancy, maternal infections and birth delivery. The main congenital infections are rubella, cytomegalovirus and syphilis.[28] Complications at birth such as, prematurity, oxygen deprivation, low birthweight, neonatal jaundice and injury also contribute to non-genetic causes of hearing loss.[1] Other factors may include toxins from certain types of drugs and Foetal Alcohol Syndrome caused by high levels of alcohol consumption by the mother in pregnancy.[27]

Babies and infants with hearing loss may exhibit a lack of or a delayed response to sound, have difficulty locating the source, are unable to hear clearly what others are saying and pay more than usual attention to speakers' facial expression and lip movement while listening.[29,30] As the child gets older, the signs of hearing loss may become more noticeable such as, delayed language development, poor attention in class, misinterpreted instructions, frequent use of gestures to express themselves and becoming easily irritated as a result of communication difficulty.[31] Hearing plays an important role in learning spoken language and for the cognitive development of children. Without appropriate, early intervention, hearing loss is a barrier to both education and social integration.[1]

1.7 Types of Hearing Loss

Classification of hearing loss can be based on the anatomic location of the problem. Hearing loss may be classified into three types: [5]

- Sensorineural
- Conductive
- Mixed Loss

Sensorineural hearing loss is the most common form of hearing impairment and occurs as a result of damage to the inner ear structures, including the cochlea and the vestibulocochlear nerve.[32] For example, an auditory neuropathy causing a failure of neural transmission of the auditory signal from the cochlea to the higher level auditory centres.[27] Sensorineural hearing loss may be unilateral or bilateral and onset can be sudden or progressive. The basis of Sensorineural hearing loss is multifactorial. Leading causes include genetic disorders, cumulative noise exposure and presbycusis. These causes are not discrete; as susceptibility to hearing loss as a result of factors such as noise and presbycusis can be influenced by genetic predisposition.[27]

The most common cause of sensorineural hearing loss is age-related and known as Presbycusis.[33] This gradual, bilateral form of hearing loss is associated with the aging process and is characterised by progressive deterioration of auditory sensitivity, loss of the auditory sensory cells and central processing functions. Common complaints associated with Presbycusis include the inability to hear or understand speech in a crowded or noisy environment, difficulty understanding consonants and the inability to hear high pitched, (high frequency) voices or noises. Tinnitus is often present.[34] Such age-related hearing loss may be attributed to genetic predisposition and physiological deterioration caused by environmental factors and modifiable lifestyle behaviours that are sustained throughout the course of life such as, unprotected occupational or recreational, continuous or intermittent exposure to loud noise.[18]

Noise induced hearing loss (NIHL) represents the most common preventable cause of Sensorineural hearing loss and develops over a period of several years as a result of exposure to continuous or intermittent loud noise.[27] The mechanism by which excessive noise induces hearing loss includes direct, mechanical damage to the cochlear structures and metabolic overload due to over-stimulation.[35]

A study which investigated the global burden of adult-onset hearing loss resulting from occupational exposure to noise reported that 16% of the disabling hearing loss in adults is attributed to occupational noise, ranging from 7% to 21% in the various WHO defined sub-regions. The effects of the exposure to occupational noise are larger for males than females in all sub-regions and higher in developing regions.[36]

Males usually experience greater exposure to noise at work than females due to differences in occupational category and economic sectors of employment, such as mining, manufacturing, utilities and construction as well as the duration and intensity of noise exposure over a working lifetime.[37]

The academic literature acknowledges that in high income countries there is a reduced occurrence of NIHL which may be associated with decreased noise exposure, improved regulation and use of protective equipment. However, this

positive trend does not apply to low and middle income countries, where exposure to high levels of noise at work remains significant.[37]

Conductive hearing loss is characterized by an obstruction to air conduction that prevents the proper transmission of sound waves through the external auditory canal and/or the middle ear. It is characterised by an almost equal loss of all frequencies.[15] This form of hearing loss may be congenital, caused by trauma, such as a membrane perforation, a chronic ear infection, such as severe otitis media, wax impaction or otosclerosis, an abnormal bone growth and fixation of the stapes bone.[8,17,38]

Mixed hearing loss may occur when a sensorineural hearing loss is compounded by conductive hearing loss.[35] For example, when an individual with an underlying age-related Presbycusis also has an acute middle-ear infection. Mixed hearing loss may also be related to developmental abnormalities affecting both the middle ear and cochlea.[17]

1.8 The Prevalence of Hearing Loss

Hearing loss is very common, it affects over 1.3 billion people worldwide and is estimated to be the fourth leading cause of disability globally.[2,39,40]

In 2008 the World Health Organisation estimated that 360 million people worldwide lived with disabling hearing loss, including 32 million children and 180 million older adults.[41]

In 2018 it was estimated that 466 million people are now living with disabling hearing loss, corresponding to a global prevalence of 6.12%.[42] This includes 34 million children and over one third of all people aged 65 years and older.[43,44]

Over the coming decades, as the worldwide population continues to grow and age, the number of people with hearing impairment is expected to increase. [45,46,15] Based on this demographic shift, it is estimated that by 2050 over 900 million people will have disabling hearing loss.[42]

[2] Hearing loss of greater than 20 dB.

The Global Burden of Diseases, Injuries and Risk Factors study, analysed data from forty-two studies conducted over four decades to explore the prevalence of hearing impairment by international region, sex, age and hearing level.

The results indicated that hearing impairment was more common among older people and among men. These results also suggest that the prevalence of child and adult hearing impairment is substantially higher in Low and Middle Income Countries (LMICs) as compared with high-income countries.[47]

As shown in Figure 4, disabling hearing loss is unequally distributed across the world.[42,48] The prevalence of disabling hearing loss in some regions is nearly four times that of high-income regions.[42] The highest prevalence is observed in the Central/Eastern Europe & Central Asia region (8.36%), followed closely by South Asia (7.37%) and the Asia Pacific (6.90%). Overall, the WHO estimate that 80% of those affected by disabling hearing loss live in LMICs.[41,49]

The higher prevalence of hearing loss in low and middle income settings may be explained by the higher rates of pre and post-natal childhood infections, use of ototoxic drugs and unprotected and excessive exposure to occupational and environmental noise.[23,45] A rising prevalence of hearing loss in adults is also attributed to an ageing population within low and middle income countries, which increases the prevalence of presbyacusis.[23]

The proportion of hearing loss due to preventable causes is also much higher in low and middle income countries (75%) than in high-income areas (49%).[1] The reasons for this may include the higher occurrence of infection and limited access to comprehensive healthcare systems incorporating, maternal, child healthcare services and vaccination programmes.[1,50,23]

Figure 4: Regional Prevalence of Disabling Hearing Loss[42]

Region	Prevalence of DHL in 2018 (%)
High Income	4.57
Central/Eastern Europe & Central Asia	8.36
Sub-Saharan Africa	4.55
Middle East & North Africa	3.17
South Asia	7.37
Asia Pacific	6.90
Latin America & Caribbean	6.18
East Asia	6.85

Global data on the prevalence of hearing loss needs to be interpreted with caution. Historically, population-based epidemiological knowledge or trends on the amount of hearing loss and its health-related consequences have not been well described.[51] This is due to differences in the definition and classification of hearing loss and difficulties with measuring hearing thresholds. In addition, the challenges with measuring activity limitations and participation restrictions induced by hearing loss.

Similarly, the WHO acknowledge the overall scarcity of epidemiological evidence regarding prevalence of hearing loss and ear diseases amongst Member States.[52] Population-based data related to prevalence and causes of hearing loss were found to be sparse across all income levels and WHO regions.[42] Inconsistent measurement across countries and regions leads to large gaps in coverage. Where data was available, it was not always representative of all sectors within each country or easy to compare with data from other studies.[52]

In particular, surveys use different thresholds (and in some cases different definitions in terms of frequencies and better or worse ear) and different age groups.[22]

Epidemiological surveys are particularly scarce in low-middle income countries.[47] This is due to a number of factors including the difficulties encountered in field testing hearing levels, limited or inconsistent diagnostic and reporting systems as

well as a lack of awareness of the problem leading to shortage of funding and expertise to conduct surveys. This lack of comparable data is attributed to the challenges that many countries experience, including;

- Limited governmental and public awareness of hearing loss and the prioritised need for epidemiological data collection
- Lack of public funding to commission such research or develop staffing capability and competence.
- Population-based surveys require the use of standard methods of classification, robust protocols and effective research tools. However, lack of research knowledge, expertise and experience may limit the quality and reliability of such studies.[45]
- The practical and logistical challenges of collecting data, measuring hearing impairment, the activity limitations and participation restrictions induced by hearing loss.[47,51]
- The political, social and ethical implications of the research outcome. Prioritising competing healthcare needs and meeting public demand for a large-scale intervention which may require long-term governmental commitment and significant financial investment.
- Limited strategic planning and resources at community and national level.[52] It is estimated that fewer than 40% of low and middle income countries have a national management plan for ear and hearing health.[53]

A few large-scale surveys of hearing loss have been conducted, from which important lessons can be drawn. In the United States the prevalence of audiometric hearing loss among all individuals (age ≥12 years) was estimated using data from a nationally representative data set and the World Health Organisation (WHO) definition of hearing loss.[3,54] This study estimated that 30 million people, or over 12% of the American population, 12 years and older had bilateral hearing loss from 2001 – 2008. This estimate increases to over 48 million, 20% of the population, when including individuals with unilateral hearing loss. Overall, the prevalence of hearing loss increases with every age decade. The prevalence of hearing loss is lower in women than in men and in Black versus White individuals across nearly all age decades.[55,56]

A large-scale, population-based study specifically designed to measure the prevalence of hearing loss in older adults living in the United States, reported that the average age of participants was 65 years (58% were women) and the prevalence of hearing loss was 46%.[57] This study also found that the odds of hearing loss increased with age and were greater for men than women. These results demonstrate that hearing loss is a very common problem affecting older adults. The prevalence of hearing loss increases with age, with up to 80% of functionally significant hearing loss occurring in older adults.[35,51]

A population based research study in South Korea, explored mean hearing thresholds and demonstrated similar age and gender-related hearing loss characteristics.[58]

An Australian study reported that in 2017, the prevalence of hearing loss was estimated to be 3.6 million or 14.5% of the population.[3] Prevalence of hearing loss is expected to more than double to 7.8 million by 2060, comprising 4.9 million males and 2.9 million females. These projections indicate that approximately one in every five people in Australia will have some form of hearing loss by 2060.[59]

In the UK it is estimated that more than 11 million people, or one in six of the population are affected by hearing loss.[4] There are also an estimated 900,000 people in the UK who have severe or profound levels of deafness. By 2035, it is predicted that there will be approximately 15.6 million people with hearing loss in the UK, representing one fifth of the population.[60,61]

1.9 Disability and Hearing Loss

The impact of hearing loss goes beyond the ability to hear different sounds, to potentially a profound impact on how people live their lives.[40] This impact may be explored using a conceptual framework, grounded in the broader literature on disability. Historically, the complexities of disability have been studied using medical and social conceptual models, and these are described here in brief.

[3,3] Measured as 25 decibels (dB) or worse loss in the better hearing ear.

The medical model primarily looks at a person's impairment and focuses on the impairment as the reason why people are unable to access goods and services or to participate fully in society. The medical model focuses on the impairment and what can be done to 'fix' the disabled person or provide special services for them as an individual.[62] The medical model of disability therefore has as its focus the origin, degree, type of loss, onset, and structural pathology of deafness, largely considering people to be disabled if they have a hearing loss. The pathology perspective focuses on the failure of the hearing mechanism and deafness is defined as a medical condition that requires remediation, either through correction or compensation.[63] This model therefore does not focus on the broader implications there may be for the person affected, nor on the role of society in alleviating the impact of disability, but rather focusing on the need for medical intervention.

In contrast, many people with a hearing impairment do not consider themselves to be disabled but identify and seek to be respected as a distinct cultural group with its own beliefs, needs, opinions, customs and language. Members of the deaf community may define deafness as a cultural rather than an audiological term.[63] In addition, there are many non-medical positive changes that can be made to alleviate the potentially negative impact of hearing loss, such as teaching alternative modes of communication (e.g. sign language) and other new skills and ensuring that laws are in place to prevent discrimination against people with hearing loss.

The social model was developed as a response to the medical model. According to the social model, a person does not 'have' a disability, disability is something a person experiences. The disability experienced is often caused by the approach taken by society/individuals which fails to take account of people with impairments and their associated needs. This can result in people with impairments being excluded from mainstream society. The social model seeks to remove unnecessary barriers which prevent disabled people participating in society, accessing work and living independently.[62] The social model of disability views a person's disability not as an individual's status, but as a problem with the way that society perceives and treats the person with an impairment.

According to this model, a disability would be alleviated by societal structures being put in place to support the full participation of people with impairments, for instance, making inclusive education universal and ensuring that offices allow the full functioning and participation of people with hearing loss.[64]

In summary, the medical model focuses on the individual's impairment and its alleviation whereas, the social model states that disability is a result of the external environment or the way society is organised and not attributable to the individual. In contrast, a less dichotomous perspective considers disability from hearing loss as a product of the dynamic and complex set of interactions between the hearing impairment, individual and the wider environment.[65,45]

The WHO International Classification of Functioning and Disability (ICF) is a theoretical framework which integrates the medical, social, and individual perspectives of health and may be referred to as a bio-psycho-social model.[66] The framework focuses on well-being and functioning, rather than on disease and disablement.[24] The ICF Model provides a framework for how the impact of a health condition, such as hearing loss may be understood.[67] Although the medical model made the impairment the focus, the social model regarded the disability to be a result of environment and not an attribute of the individual. The ICF may be considered as an amalgamation of both medical and social models of disability.[24] The ICF Model is illustrated in Figure 5 and the key components of the framework are defined and applied to hearing loss below.[66]

Structure and Function relates to the anatomical parts of the human body such as the organs and limbs and the physiological processes observed in the circulatory, nervous or respiratory system. With hearing loss, this affects the organs of hearing, the ears and internal audiological system.

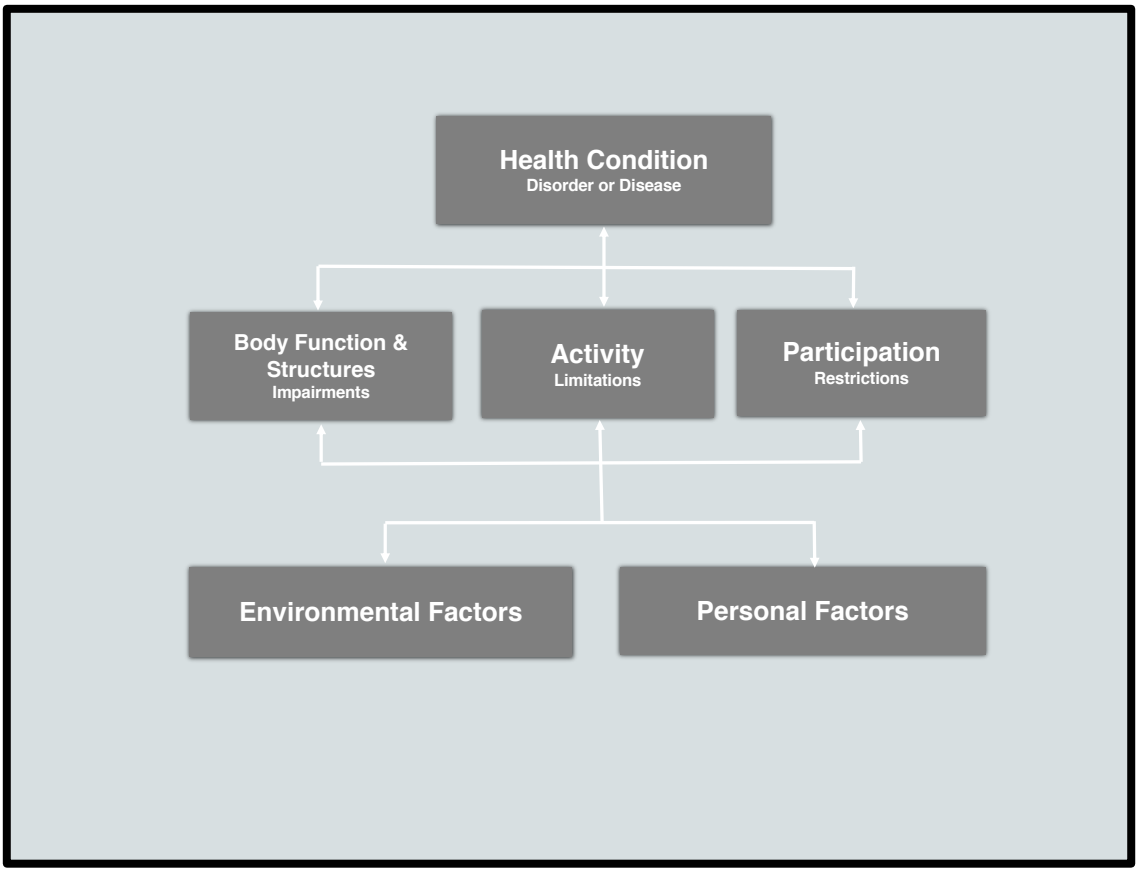
Impairments are the significant deviation or loss in body function or structure. Hearing impairment is caused by an anatomical or physiological deviation in the structure and function of the ear or auditory nerve which may result from a health condition.

Activity is a task or action which is performed by an individual (e.g. walking, bathing, using the telephone) The limitations are the challenges an individual may experience in executing activities, such as diminished sound detection, speech recognition and understanding.

Participation is defined as the involvement in a life situation or event (e.g. having a job, going to school). Participation restrictions are the challenges that an individual may encounter whilst engaging in a life event, such as being employed, attending and contributing to social events or accessing health services.
Personal and Environmental Factors comprise of the physical, psychological and social context in which people live and conduct their lives. The impact of a health condition on impairment and ultimately on activity and participation will depend on the individuals specific environment, personal and social characteristics and these factors may facilitate, or be a barrier to successful functioning.[18] Disability and functioning are viewed as outcomes of interactions between health conditions (e.g. diseases, disorders or injuries) and these contextual factors.[65] For example, with disability attributed to hearing loss, the impact on activities and participation will be heavily influenced by environmental factors such as noise, lighting levels and the physical distance between the source and the listener as these will significantly impact on the ability to communicate and the quality of the interaction.[68]

The ICF Model was used as a classification method and reference tool in a cross-sectional survey which identified the relevant aspects of functioning, disability, and contextual factors for adults with hearing loss.[69]
The content analysis identified that the most frequently reported aspects of the activity and participation restrictions that resulted from the hearing impairment related to difficulties in communication. The most important environmental factors mediating this association related to the physical environment, specifically background noise and the use of hearing aids. Personal factors, such as confidence and emotional function were specifically highlighted as influencing the impact of hearing loss on poor mental health. The study concludes, that these results emphasise the utility of the ICF Model as a multi-dimensional tool for assessing the holistic impact for persons with hearing loss.

Figure 5: The International Classification of Functioning & Disability Model [24]



This conceptual, broad-based classification of functioning and disability has been used to structure and scope the review of the academic literature, to understand the meaning of disabling hearing loss and to explore how it impacts on people's lives.

1.10 Impact of Hearing Loss

> 'Communication defines us and underlies our ability to function in the world, to relate to family, friends and partners, have a job, lead productive lives and maintain our health and wellbeing through social connections.' [108]

In this introductory section the impact of hearing loss is explored from a multi-dimensional perspective using the ICF framework, with reference to key activities, participatory events and context-specific environmental and personal factors. Depending on the age of onset and its severity, hearing loss can lead to a chronic, lifelong disability. For all ages and for both sexes, hearing loss may cause difficulties with activities involving interpersonal communication.[70]

Adults with hearing loss report difficulty in a range of activities, specifically those that require social interaction and communication. A cross-sectional study of older adults in the United States investigated the degree to which hearing-loss severity had an impact on activities of daily living such as bathing, dressing and eating and instrumental activities of daily living such as, using the telephone, completing light housework, laundry and managing money. The analysis demonstrated significant trends in the proportion of people reporting difficulties with both forms of activity of daily living, by degree of hearing-loss severity, beginning around the age 60 years.[71]

Specific challenges include communicating with background noise, over the telephone or in situations requiring extended periods of listening such as the cinema or church. Such communication difficulties may lead to multiple negative consequences, including poorer quality of life, social isolation, and depression.[23] Hearing impairment has also been associated with lower self-reported physical functioning and may contribute to a loss of functional independence.[72]

The communication challenges associated with hearing loss may lead the individual to withdraw from social activities and events. Participation has been defined as involvement in a life situation and engagement in a social domain, such as family relationships, community life, employment, education and recreation and leisure.[73] The person may find it difficult to fully participate in society, for example, engaging in work, attending school or accessing health services. A large study in Japan examined the consequences and gender differences of early-onset hearing loss on several social and health measures, including employment, marital status, smoking behavior and psychological distress. The findings suggest that hearing loss is related to social and health issues in daily life, including a lower likelihood of marriage, more frequent smoking, and poorer mental health, especially in women.[74]

The impact of hearing loss on participation is explored below in more detail, giving examples from the literature with respect to the impact on education, employment, quality of life and mental health and social participation.

1.10.1 Impact on Education and Employment

Several research studies have shown that children with severe hearing loss have lower literacy compared to their 'normal hearing' peers, and their educational attainments are greatly compromised.[40] The consequence of hearing loss include significant delays in language development and academic achievement.[75] Similarly, a national survey conducted in the USA showed that people with hearing loss were three times more likely to have lower educational attainment as compared with those with normal hearing.[76,77] A survey from Brazil also showed that people with hearing loss had fewer years of formal schooling.[78]

Hearing loss may also affect participation in employment. A seminal study from the United States acknowledges that at the beginning of the last century at least 80% of the American labor force were primarily employed in manual tasks that were easily undertaken by people with communication disorders such as hearing loss.[79] In comparison, at the end of the century over 62% of the labor force made their livelihood using skills based on their communication abilities. As such, communication disorders affecting hearing and speech are associated with an

unemployment rate of 42% compared with 29% for the same working-age population without disability in the United States. The income for the hearing impaired was 40% to 45% of the income of the non-hearing impaired population. In conclusion, the study argues that communication disorders reduce the economic output of the United States, whose economy has become dependent on communication-based employment.[79]

An Australian survey showed that hearing loss was associated with a decreased rate of participation in employment of between 11-17%.[80] People with hearing loss were also less likely to be found in highly skilled jobs and were over-represented among low income earners. Hearing loss was also independently associated with a lower income and unemployment or underemployment, which contributed to economic hardship. Similarly, in Brazil a cross-sectional household survey showed that people with hearing loss had a lower income.[78]

Several studies have shown that adults with hearing loss are over represented in early retirement. Women with hearing loss are less represented in the workforce, partly in comparison to men with hearing loss, but also in comparison to the female population as a whole.[4] Adults with hearing loss also experience negative psychosocial consequences at work, showing emotional distress due to misinterpretations of external information and lack of control of their work and in the work environment.[4]

Such exclusion from participation in school and work may have a socio-economic impact, leading to poverty, while also resulting in reduced intellectual and cultural stimulation and an increasingly passive and isolated existence with consequently poorer mental health and quality of life.[14] It is also a violation of the rights of people with hearing loss, as set out within the United Nations Convention on the Rights of Persons with Disabilities.[81]

The purpose of the Convention on the Rights of Persons with Disabilities is to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity.[81] In a report based on a survey of 93 countries and the lives of deaf people, it concluded that relatively few countries deny deaf people access

to education, government services or equal citizenship on the basis of deafness alone.[82] However, lack of recognition of sign language, lack of bilingual education, limited availability of interpreting services and widespread lack of awareness and knowledge about the situation of deaf people deprive most deaf people of access to large sections of society. In Mexico and most countries within Central America and the Caribbean region, deaf people have the right to get a job and earn a salary, but only seven countries have employment-based anti-discrimination legislation. Reasons provided for unemployment among deaf people in the region include, lack of employment opportunity, the low level of education and communication difficulties.[82]

1.10.2 Economic Impact

Attempts have been made to estimate the economic impact of hearing loss, at an individual and societal level, mostly from the USA. A study from the USA showed that people were predicted to lose between $220,000 and $440,000 in earnings over their working life due to hearing loss, predominantly due to reduced work productivity.[83] It was estimated that people who experience severe to profound hearing loss before retirement, are expected to earn only 50% to 70% of their peers without hearing-impairments.

Another study from 40,000 households in the USA, demonstrated that hearing loss negatively impacted on household income by an average of $12,000 per year, depending on the degree of hearing loss.[84] A third US study estimated that severe to profound hearing loss is expected to cost society $297,000 over the lifetime of an individual. Most of these losses (67%) are due to reduced work productivity, although the use of special education resources among children contributes an additional 21%. Lifetime costs for those with pre-lingual onset exceed $1 million.[85]

For people living in the USA who experience the onset of a severe or profound hearing loss at age 65 years or older, lifetime costs associated with managing hearing loss have been estimated at $43,000 per person, an estimate that includes their lower workforce participation and their reduced wages compared with people who do not have this degree of hearing loss.[83] As the number of individuals who either desire to or need to remain in the workplace beyond age

65 increases, the societal impact of hearing loss will become increasingly important.[86]

From a national perspective, the economic impact of hearing impairment can be extremely large. In 1999, one of the first economic impact studies estimated that the combined cost of communication disorders to the US economy was between $154.3 and $186 billion dollars per year, which was 2.5% to 3% of the predicted Gross National Product (GNP) for the United States.[79]

A more recent study from the Unites States estimated that for the 24 million hearing-impaired individuals who do not use hearing aids, the impact of untreated hearing loss is quantified as loss of earnings, in excess of $100 billion annually.[84] The cost to society may exceed $18 billion due to unrealised taxes. In addition to lost earnings and taxes, there may also be an impact at national level due to the health system costs.

In New Zealand a research study provided an estimate of the overall health system expenditure on hearing loss. The key findings showed that the total health system costs due to hearing loss were estimated to be about $132 million in 2016, or $150 per person with hearing loss. The largest component of health system expenditure was estimated to be on health professionals conducting hearing tests, fitting hearing aids and other services provided by audiologists and audiometrists ($78 million), followed by non-admitted hospital expenditure ($19 million) and out-of-hospital medical services. ($17 million). The New Zealand Government bore the majority of health system costs (83%), while individuals bore 10%, and other parties (such as private health insurers and charities) bore the remaining 6%.[87]

Productivity costs associated with hearing loss in New Zealand were also estimated, including lost productivity for people with hearing loss and lost productivity for people who care for people with hearing loss. The key findings demonstrate that the productivity loss in individuals with hearing loss was over $552 million in 2016, or $627 per person with hearing loss.

Individuals ($299 million) and government ($215 million) bear most of these costs. The productivity cost is largely due to losses as a result of reduced employment ($387 million). The productivity loss due to informal care was $100

million in 2016, or $114 per person with hearing loss. Individuals bear most of these costs ($61 million), with government bearing the rest ($39 million).
Each informal carer is estimated to provide over 5 hours of care per week to people with hearing loss.[87]
In an Australian study, the impact of both the financial costs and the loss of wellbeing from hearing loss were explored. The report concluded that financial costs of hearing loss in 2017 were estimated as $15.9 billion. These predominantly comprised of health system costs of $881.5 million, or $245 per person with hearing loss, and productivity losses of $12.8 billion, or $3,566 per person with hearing loss, most of which was due to reduced employment of people with hearing loss ($9.3 billion).[59,88]

As these studies have shown, unaddressed hearing loss may pose a considerable economic impact on the person and their family, the wider community and the country. This economic impact is attributed to loss of earnings and productivity and increasing demands for health care services and education.[89]
In a 2017 report produced by the World health Organisation the annual cost of unaddressed hearing loss was estimated to be in the range of $750–790 billion globally.[90] This analysis was hampered by the absence of country-specific data, especially from low and middle-income countries and does not take into consideration the costs associated with providing informal care, pre-school learning and higher education for people with unaddressed hearing loss. As such, the financial cost of addressing hearing loss is considerable and may be challenging for LMIC's.

1.10.3 Impact on Quality of Life

Hearing loss may be related to poorer quality of life.[86] The impact of hearing impairment on health-related quality of life has been demonstrated across several population-based studies using different validated instruments. Several large-scale studies in the United States and Australia have shown that older adults with hearing impairment score worse on both the physical health and mental health

components of the survey. These scores also worsen with severity of hearing loss. Limited data is available from LMICs.

One study conducted in Yemen showed that self-reported quality of life was significantly lower among people with hearing loss.[91] This difference was attributed to feelings of isolation, lower productivity, self-esteem and decreased social activity participation. One explanation for the lack of data on the impact of hearing loss on quality of life from LMICs is that the measurement tools applied in high income settings may not be suitable or appropriate for LMICs.

A research study in Nepal reported that no suitable measures exist, therefore the study aimed to amend and translate a set of established tools and assess the impact of ear disease and the effect of surgical intervention on quality of life.[92] The study concluded that ear disease in Nepal is associated with reduced quality of life and surgical intervention is associated with improved quality of life. The study acknowledged that there are few measures suitable for low and middle income-countries and it is essential to invest in such measures to guide health interventions.

1.10.4 Impact on Mental Health & Cognitive Function

Hearing loss may contribute to poorer mental health and well-being, as demonstrated by studies from high income settings. A USA study showed that hearing loss was significantly associated with depression, particularly in women.[93] Similarly, in a large-scale survey in Norway, hearing loss was associated with depression and poorer ratings for self-esteem amongst young and middle-aged people.[94] Possible explanations given for this association were that hearing loss may produce social isolation, distorted communication and in some cases stigmatisation, which may affect mental health and quality of life. However, the study from Norway found that mental health seemed to be unaffected in older adults with hearing loss. The authors conclude that this lack of correlation is most likely because the stigma attached to hearing loss disappear when subjects grow older because hearing loss is considered ‘normal’ in the older population.[4,94]

The results from an Australian study which investigated the effects of dual (hearing and vision) sensory loss on mental health, demonstrated that higher levels of depressive symptoms were associated with hearing loss and dual sensory loss, but not visual loss.[93] Greater rates of change in depressive symptoms were also evident after the onset of hearing loss and the associations between depressive symptoms and sensory loss were explained by difficulties with activities of daily living and social engagement. The study concluded that visual and hearing loss are highly prevalent among older adults and their co-occurrence may compound their respective impacts on health and functioning, thereby exerting strong effects on the mental health and wellbeing of those affected.

A population-based study in Taiwan investigated sensory hearing loss as a risk factor for depression by using a matched cohort and a 12-year follow-up period.[95] This longitudinal study in Taiwan investigated the relationship between the prevalence of sensory hearing loss and the incidence of depression over a 12-year period. The results indicated that acquired sensory hearing loss may increase the risk of subsequent depression. Sensory hearing loss was an independent risk factor regardless of sex, age and comorbidities. There was a strong association between hearing loss and subsequent depression among Taiwanese adults of all ages, particularly those aged 49 and >65 years and without using steroidal medication for the treatment of sensory hearing loss was observed. The study concluded that further clinical and biomedical studies on the relationship between hearing loss and depression are warranted.[95,96]

Hearing loss has also been associated with poor cognitive performance and the development of cognitive decline and dementia.[97,98]
In a large US study, the association of hearing loss with cognitive impairment in a population of older adults over a 6-year period was investigated.[99]
The results demonstrated that hearing loss is independently associated with accelerated cognitive decline and incident cognitive impairment in community-dwelling older adults. The magnitude of these associations was clinically significant, with individuals having hearing loss demonstrating a 30% to 40%

accelerated rate of cognitive decline and a 24% increased risk for incident cognitive impairment during a 6-year period compared with individuals having normal hearing. The study concluded that further research is required to investigate what the mechanistic basis of this association is and whether such pathways would be responsive to aural rehabilitation.[99]

A large research study in Germany investigated the effect of hearing impairment on dementia incidence in a longitudinal study of persons aged 65 and older.[100] The study also aimed to determine whether ear, nose, and throat (ENT) specialist care, care level, institutionalisation, or depression mediates or moderates this pathway. The results indicated that hearing impairment increases the risk of dementia incidence. Significant interaction between hearing impairment and specialist care, care level, and institutionalization, indicated moderating effects whilst the effect of hearing impairment was only partly mediated through ENT specialist utilization. The study concluded that preserving hearing ability and providing early treatment of hearing impairment may maintain social participation and may reduce the negative impact associated with dementia. The study also recommended further research into the impact of hearing aid use and its potential role as an intervention that may delay or prevent the occurrence of dementia.

1.10.5 Impact on Social Participation & Relationships

A Korean study examined the impact of hearing loss on social contact among older adults.[101] The results indicated that higher levels of hearing loss were associated with fewer social contacts among older adults in Korea. The place of residence was found to be a significant moderating factor; the negative impact of hearing loss on social contacts was more pronounced among those who live in urban areas, suggesting that social isolation and a lack of social cohesion in the community may play an important role.

Hearing loss is a health condition that does not only impact on the affected person. Family members or other *significant others* may be affected.[102,68,103] Partners of adults with hearing loss experience tension, effort, fatigue, frustration,

anger and guilt due to the social dependence of the affected spouse and the imposed restriction of leisure activities and social events.[104]
The significant other may act as an interpreter and be responsible for maintaining social activities and communication in the relationship and can play an important role as the primary influencer and motivator for accessing and actively participating in audiological rehabilitation.[105]

Few population-based studies have assessed the impact of hearing impairment on a spouse or partner.[72] An Australian study proposed that family members of individuals with hearing loss may experience 'third-party disability' which may adversely affect their participation in a wide range of social activities.[102] Hearing loss may impact on a third party's communication, for example, social interactions requiring frequent repetition, less frequent, spontaneous social conversation and activities of daily living such as talking on the phone or watching TV may lead to frustration and avoidance of social situations.[102]
Maintaining the relationship is difficult for people with profound hearing loss, generating extensive relationship tension and above-average divorce and separation rates.[104] A research study found that the most satisfied relationships are among couples in which the partner rates the hearing loss as less severe than does the affected person.[106]
In summary, the consequences of hearing loss may limit a partner's social opportunities, increase the burden of communication and decrease self-perception of quality of life and satisfaction in their relationship with the partner with hearing loss. [24]

1.10.6 Hearing Loss & Mortality

There are a number of studies that associate an increased risk of mortality with hearing loss.[87] In one large scale, longitudinal study that investigated whether audiometric hearing loss is associated with mortality in older adults living in the USA, results demonstrated that hearing loss is associated with increased mortality, independent of demographic characteristics and cardiovascular risk factors.[107]

Hearing impairment has been linked to all-cause mortality through three mediating variables: disability in walking, cognitive impairment, and self-rated health.[108] Hearing loss has also been significantly associated with an increased risk of falls.[109] The suggested mechanisms include confounding factors with shared conditions such as increased brain processing and concentration requirements, vestibular (balance) loss and degeneration with ageing, postural instability and limitations in spatial awareness.[107] Finally, it is possible that other conditions which contribute to hearing loss may be the direct cause of death. For example, a small number of deaths could arise from otitis media in Pacific Island countries due to resultant complications such as abscess, meningitis and thrombosis.[110] Overall, hearing loss appears to be significantly associated with a 10% increase in mortality for those that are over the age of 70 years and have moderate or worse hearing loss.[87]

In summary, this section of the introduction has explored the multi-dimensional impact of hearing loss on activities and participation and other key outcomes. This descriptive review of the literature has demonstrated that lack of data in general, but also specifically from LMICs, on the association between hearing loss and poverty, education and employment. All these difficulties are magnified in developing countries, where there are generally limited services, few trained staff members, and little awareness about how to deal with these difficulties.[70]

1.11 Interventions to Address Hearing Loss

The WHO estimate that about half of hearing impairment in all age groups could be avoided, treated or prevented via known and proven methods.[111]

Aural rehabilitation is a key strategy for treatment of hearing loss as it aims to reduce hearing loss and thereby improve functioning, participation and quality of life.[112,41]

Aural Rehabilitation is comprised of several elements, sensory management, instruction, perceptual training and counselling.[112] Aural rehabilitation may be conducted with groups or individuals, in person or using home-based IT-enabled models or a combination of these methods.[113]

An effective approach to rehabilitation which seeks to help and support the individual to overcome difficulties in daily life should involve several key steps including, identifying individual needs, setting specific goals, making shared informed decisions and supporting self-management.[114] Consequently, an aural rehabilitation programme should be structured, systematic, individualized, and goal-directed. Although aural rehabilitation programmess are accepted and widely used in the management of hearing-impaired individuals, the role of aural rehabilitation in overall treatment and its impact on health outcomes has not been clearly evaluated.[15]

Sensory management is a key focus of aural rehabilitation, and this may be addressed through the provision of technological devices, of which hearing aids are the most common form of intervention.[111] The hearing aid is designed to receive, amplify and modulate sound for the wearer. It has three basic parts: a microphone, amplifier, and speaker. The hearing aid receives sound through a microphone, which converts the sound waves to electrical signals and sends them to an amplifier. The amplifier increases the power of the signals and then sends them to the ear through a speaker.
With technological advancement, the style, available features and cost of hearing aids vary considerably. Based on the position of fitting, behind-the-ear (BTE) styles of hearing aid consist of a hard-plastic case which is worn behind the ear and contains the electronic components. The case is connected to a plastic ear-mold that fits inside the outer-ear. Sound travels from the hearing aid through the ear-mold and into the ear. Such devices are used by people of all ages for mild to profound hearing loss. In contrast, the discreet 'In-the-Ear' (ITE) or 'Completely-in-Canal' (CIC) hearing aids fit completely inside the outer ear and are used for mild to severe hearing loss.[115]

A hearing aid does not restore normal hearing or repair the underlying damage that has occurred to the sensory system, but it can improve sound detection and speech understanding within different listening environments.[86]
Hearing aid fitting is an important part of adult rehabilitation and there is also evidence that fitting hearing aids when people first begin to experience hearing loss may result in better long-term outcomes than when hearing aid fitting is

delayed.[18] Most people require a period of adaptation before deriving the full benefit of a hearing aid.[72] Instruction involves teaching people how to effectively use the technology and create optimal listening environments. There is evidence to support the conclusion that formal instruction in hearing aid and accessory management leads to increased usage and therefore, enhanced function and activity over time.[112]

Despite the potential benefits of hearing aids to communication ability and quality of life, only about 40% of adults aged 70 years and older who could benefit from hearing aids use them.[116] The most commonly cited reasons for lack of use were cost, inconvenience, the poor experience of others and perceived lack of need.[117] Several studies have acknowledged poor hearing aid adherence and this so-called 'in the drawer' phenomenon may be related to lack of perceived benefit or the high cost of batteries. Among older adults, other medical conditions such as reduced manual dexterity or poor visual acuity may reduce the ability to position or maintain the hearing aid. It is acknowledged that up to 40% of people fitted with a hearing aid choose not to use them.[117]

A Cochrane Review was conducted in order to investigate if there were any interventions that could help people to wear their hearing aids more frequently.[118] The review identified 37 studies involving a total of 4129 people which were a mix of new and experienced hearing aid users. Most of the study participants were aged over 65 and from a high-income country. The vast majority of studies examined the methods used to help someone effectively manage their hearing loss and hearing aid(s). The methods employed included providing information, practice and experience at listening and communicating tasks or by asking people to engage in practice tasks at home.

These forms of self-management support did not provide any evidence that showed that such interventions helped people to wear their hearing aids more frequently, for more hours per day over the short, (12 weeks) medium (12-52 weeks) or long term. (1+Year) However, by providing self-management support people reported a lower level of 'hearing disability' affecting their engagement in activities and improved verbal communication over the short term. When this was combined with changing how the support was delivered, people also reported slightly more hearing aid benefit over the long term.

Only six studies (287 people) reviewed or measured how people were progressing after a year or more. The study reported that complex interventions that deliver self-management support in different ways, improve some outcomes for some people with hearing loss who use hearing aids. However, no interventions that increased self-reported daily hours of hearing aid use were identified.[118]

Few studies measured how many people use hearing aids compared to how many are fitted (adherence). The many factors that might increase daily hours of hearing aid use or encourage more people to wear their hearing aids have not been tested. The review concluded that It was difficult to combine data across different studies because many outcome measures were used and comprehensive results were not available or fully reported. Longitudinal outcome studies were also lacking. The evidence was judged to be of low quality and there was risk of bias (population size and type restrictions and inconsistent or non-standardised reporting) in the way many of the studies were conducted.[118]

1.12 Other Components of Aural Rehabilitation

One of the central goals of hearing aid prescription is to restore the acoustic cues needed for accurate phoneme processing. However, in most cases hearing aids alone are insufficient to restore normal consonant identification.[119]

As a result, recent research programmes have focused on the potential benefits of perceptual training. Perceptual training can improve the types of listening skills needed to enhance speech perception.[119] Hearing loss impairs the ability to identify phonemes, particularly consonants, by degrading the acoustic cues available for understanding conversational speech. Perceptual training enables experienced hearing aid users to improve their listening performance, restoring their ability to identify some consonants into the normal range. Thus, remediating consonant-identification deficits through perceptual training is considered a promising approach to audiological rehabilitation.[119]

Counselling is also crucial to a successful and effective aural rehabilitation program.[120] Audiology professionals may employ counselling skills when working with patients and their communication partners. These techniques may help

people to confront a range of psychological, social and emotional concerns, in recognising their hearing-related problems and attempting to acknowledge, understand and adjust to the realities of living with such challenges.[114] Counselling may also be used to manage any residual limitations and encourage social participation.[18]

There are two types of counselling styles or techniques that may be used within the aural rehabilitation domain.[120] Firstly, educational counselling is content-based and is related to the informative aspect of counselling. This includes information regarding the type, degree and configuration of the hearing loss, etiology and treatment for hearing loss. Supportive counselling, involves both the emotional and affective features of counselling, and aims to help the person with hearing loss through the emotional response to hearing loss as well as the grieving process, transitioning from denial to acceptance.[120]

A research review conducted in Chile aimed to determine the effectiveness of auditory rehabilitation programmes focused on communication strategies.[121] The study concluded that rehabilitation options such as hearing aid fitting and communicative programme involvement were associated with improvements in social participation and quality of life in patients with hearing loss. Group auditory rehabilitation programmes were effective in reducing activity limitations and social participation restrictions, and thus improve an individual's quality of life.
Similarly, a small-scale intervention study in Saudi Arabia demonstrated that amongst working age adults who were new to using a hearing aid, the provision of a short, individualised auditory rehabilitation intervention programme yielded a significant improvement in the performance of hearing impaired adults by enhancing the benefits of hearing aid use.[122]

1.13 Impact of Hearing Aids

Based on the ICF framework, the goal of amplification with hearing aids is to reduce the auditory deficits associated with body functions and structures, thereby reducing activity limitations and participation restrictions.[4]

Hearing aids aim to reduce the impact of hearing loss and to improve a person's ability to take part in everyday life.[123]

In 2012 it was estimated that 11 million hearing aids were sold worldwide and although hearing aids are the most common technology for adults with hearing loss and are in widespread use, few studies have evaluated their effectiveness and impact.[3] A systematic review with meta-analysis aimed to evaluate the effect of hearing aids on health-related quality of life in adults with sensorineural hearing loss. Sixteen studies from 2004 met a priori criteria for inclusion in the review. The review concluded that hearing aids improve adults' health-related quality of life by reducing psychological, social, and emotional effects of sensorineural hearing loss. The study recommended that future studies should include control groups using randomized controlled trials.[123]

A more recent Cochrane literature review incorporated five randomised controlled trials (RCTs) from high income-settings including the USA and Europe, and involved 825 participants, published between 1987 and 2017.[124] The review found evidence that hearing aids have a large beneficial effect in improving the ability of adults with mild to moderate hearing loss to participate in everyday situations and improved their ability to listen to other people. The review also noted that hearing aids have a smaller, but beneficial effect in improving general health-related quality of life, such as physical, social, emotional and mental well-being. The review recommended that any future studies should measure and report on benefits consistently and separately for different age groups, genders, levels of hearing loss and types of hearing aids.

The available evidence therefore concurs that hearing aids are effective at improving hearing-specific health-related quality of life, general health-related quality of life and listening ability in adults with mild to moderate hearing loss. This evidence is compatible with the widespread provision of hearing aids as the first-line clinical management in those who seek help for hearing difficulties.[124]

In contrast, an observational study which aimed to clarify the impact of hearing aids on mental health, social engagement, cognitive function and physical health outcomes in older adults with hearing impairment in the United States, concluded that although hearing aids may reduce the 'hearing handicap' and promote better

perceived quality of physical health, there was no evidence that hearing aids promoted cognitive function, mental health, or social engagement in the long term.[98] Previous studies had not examined outcomes over such a long duration and the main strength of this study was that a wide range of outcomes were examined in a population-based sample over 5 to 11 years post baseline. However, the proportion of hearing aid users in the study was small. (10% at baseline) and this may explain the lack of impact detected.[125]

Hearing loss is associated with poor cognitive performance and incident dementia and may contribute to cognitive decline.[98] Treating hearing loss with hearing aids may potentially ameliorate cognitive decline. A UK study of adults aged 40 to 69 years aimed to test whether use of hearing aids was associated with better cognitive performance, and if this relationship was mediated via social isolation and/or depression.[98] Structural equation modelling of associations between hearing loss, cognitive performance, social isolation, depression and hearing aid use was carried out with adults who completed a hearing test.

The study found that hearing aid use was associated with better cognition, independently of social isolation and depression, and after controlling for age, sex, general health and socioeconomic status as potential confounders.

These findings were consistent with the hypothesis that hearing aids may improve cognitive performance, although if hearing aids do have a positive effect on cognition it is not likely to be via reduction of the adverse effects of hearing loss on social isolation or depression. The report suggests that any positive effects of hearing aid use on cognition may be via improvement in audibility or associated increases in self-efficacy. Alternatively, positive associations between hearing aid use and cognition may be accounted for by more cognitively-able people seeking and using hearing aids. Further research is required to determine the direction of association, if there is any direct causal relationship between hearing aid use and better cognition, and whether hearing aid use results in reduction in rates of cognitive decline measured longitudinally.[98]

In contrast, a study which aimed to assess the effects of increasing auditory acuity by providing hearing aids to subjects with dementia who have mild hearing loss, concluded that hearing aids do not improve cognitive function or reduce

behavioural or psychiatric symptoms. However, the presence of dementia should not preclude assessment for a hearing aid as they are well tolerated and reduce disability caused by hearing impairment.[126]

A study from the Netherlands aimed to determine the cost-effectiveness of fitting hearing aids in adult hearing-impaired persons, as with compared with not fitting them.[127] This study considered societal cost, consisting of the extra health care and non–health care costs in comparison to the financial savings resulting from the possible gain in productivity associated with the intervention. The direct health care costs included in the study were medical consultations, diagnostics (audiometry), hearing-aid fitting, the hearing-aid instrument and hearing-aid use (batteries and repair). Possible savings in terms of increased productivity were assessed in the prospective study of first-time fitting of hearing aids.
The average costs of fitting hearing aids in a population of persons with hearing complaints amounted to 781 Euro (base-case estimate, discounted). Of this amount, 60% is spent on hearing aids, 16% on hearing-aid batteries and repair, and 14% on direct health care costs.
Overall health-related quality of life was measured using a five-dimensional (EQ-5D) questionnaire. On the basis of this estimate, fitting of hearing aids is considered a cost-effective health care intervention.[127]

In summary, as part of an aural rehabilitation programme, hearing aids are considered the most effective and cost-effective way of making a major difference to the quality of life of hearing impaired people and may contribute to the economic independence of affected individuals, although few studies have examined this association and these have been predominantly in high income settings.[127]

1.14 Hearing Aids in Low-Middle Income Countries

More than 80% of the global population with hearing loss live In low-middle income countries (LMICs) and given present demographic trends, this proportion is predicted to increase in the future.[40,128] Currently, hearing instrument technology and research is almost entirely focused on the projected needs of the

consumer market in high-income countries. Approximately 90% of the global market in hearing aids is supplied by six European and North American manufacturers who focus predominantly on producing high-cost devices with advanced sound-processing features.[129] While, these products are of high quality and often provide very effective rehabilitative support, their purchase is often not feasible for a people living in a LMIC.[129]

Hearing aids must be affordable and this has been a long-standing barrier to access. As a consequence, despite the potential positive impacts of hearing aids, there are currently large gaps in coverage and accessibility. The international production and supply of hearing aids meets less than 10% of global need and within LMICs, fewer than 3% of those who need hearing devices have access.[52] Such low coverage may have a large societal impact, as described above. It is acknowledged that in LMICs, amplification requirements and other hearing health needs may differ from those in high-income settings, for a variety of cultural, environmental, health or economic reasons. For instance, high humidity and the effect on componentry, prohibitive device cost and access to batteries, repair and maintenance services.

New advancements in device research and technology may address some of these specific requirements such as, the provision of an alternative energy supply and the use of solar-powered devices, less-expensive and improved electronic componentry and functional, water-resistant casings. Such provision would make hearing aids more accessible, affordable and reliable for use in challenging environments.[128]

A primary obstacle to hearing aid provision in LMICs is their cost. There is likely to be a large unmet need for innovative interventions including low-cost hearing aids in developing countries.[47] The reason for such polarized usage is that in LMICs the cost of acquiring and maintaining such devices remains prohibitive for most potential users.[45] Equally, within LMICs 80% of people with hearing loss cannot access hearing healthcare services because of lack of availability of audiologists or other relevant healthcare workers.[52] Even when hearing aids are available, however, this does not translate into their use.[130]

The main reasons for this are not fully understood and few empirical studies have been undertaken to assess the barriers to use. Identifying factors that affect hearing aid usage are therefore necessary for devising appropriate rehabilitation strategies to ensure greater use of hearing aids.

Only few, small scale impact studies have been conducted in LMICs, and these show that the use of hearing aids have been shown to improve quality of life and mental health.[131,132] A small (n=37) interventional research study in Turkey aimed to investigate the cognitive and psychological impact of using hearing aids among an elderly population.[131] The results of the study showed that within three months of using a hearing aid there was a significant reduction in depressive signs and improvements in psychological state and mental function. Similarly, a small study (n=50) in Brazil aimed to investigate the impact of hearing aids on the quality of life of an elderly population.[132] A significant improvement in self-assessed quality of life across a wide range of domains including, functional, emotional, social and mental health was observed after provision of hearing aids.

1.15 Summary

This review of the literature has identified the multi-dimensional impact of hearing loss and demonstrated the impact on impaired activities of daily living, a reduced quality of life, diminished mental health and well-being and economic disadvantage. The important role of aural rehabilitation in alleviating these impacts has been acknowledged and the cost-effective and positive impact of hearing aids has been identified and described. This review has also demonstrated that in low resource settings, where the greatest need may be, the availability of hearing aids and aural rehabilitation may be limited and research data and information is sparse and often of low quality.

1.16 Study Rationale

This introductory chapter has defined the research domain and explored the current body of knowledge. It has provided a definition and classification for hearing loss, described the anatomy and physiology of the auditory system and discussed the causes of hearing loss and its prevalence. A conceptual framework based on the ICF model of disability has been proposed from which the impact of hearing loss has been explored and the concept of audiological rehabilitation has been discussed.

The key purpose and rationale for this research project has been generated from the synthesis of data and is presented below:

- The prevalence of hearing loss is high, particularly in LMICs and is likely to increase further with a global ageing population.[45]
- Hearing impairment is associated with poverty and lack of employment, impaired activities of daily living and reduced quality of life and mental well-being.
- Hearing aids appear to be cost effective and may alleviate the negative consequences of hearing loss.
- The studies that have investigated the impact of hearing loss and hearing aids are predominantly from high income settings. Only a limited number of small studies have been undertaken in LMICs.
- Many people who are offered hearing aids, or have received them, may not use them regularly.[130] The main reasons for this are not fully understood and specifically within LMIC's, few empirical studies have been undertaken to assess the barriers to use.

The specific purpose of this research project is to address the evidence gap relating to the impact of hearing loss and the potential benefits of hearing aids. The outcomes from this research will help to provide an evidence-based foundation from which audiological rehabilitation programme planning in a LMIC is facilitated and programme funding, resource allocation and wider health-system development is promoted.

1.17 Research Aim & Hypothesis

The aim of this study is to assess the impact of hearing impairment and the provision of hearing aids on poverty, mental health, quality of life and activity participation of adults living in Guatemala.

Hypothesis: Hearing aids have a positive impact on measures of poverty, quality of life and mental health among a low-income population of adults with disabling hearing loss living in Guatemala.

Null Hypothesis: Hearing aids do not impact on measures of poverty, quality of life and mental health among a low-income population of adults with disabling hearing loss living in Guatemala.

1.18 Objectives

Based on an adult population in Guatemala, Central America, the objectives of the study are to:

- Compare socio-economic status, quality of life, mental health and functional activity and participation between individuals with hearing loss and age, sex-matched adults without hearing loss.
- Evaluate the impact of hearing aid provision on socio-economic status, mental health, quality of life and functional activity participation.
- Assess hearing aid usage among those referred for services.
- Explore the barriers and facilitators to uptake and usage of hearing aids among those referred for services.
- Assess patient satisfaction with hearing aids among hearing aid users.

1.19 Research Study Location

This research project was conducted in Guatemala. (Figure 6) The Republic of Guatemala has a growing population of over 15.5 million people and is the most populous country in Central America.[133] Guatemala is relatively poor, and economically, the Gross Domestic Product (GDP) per capita is approximately half the average for Latin America and the Caribbean. The agricultural sector accounts for almost 14% of GDP and 31% of the labour force. The key agricultural exports include sugar, coffee, bananas and vegetables.[134]

Figure 6: Map of Guatemala[135]

Guatemala has one of the highest inequality rates in the Latin American & Caribbean region, with the richest 20% of the population accounting for more than 51% of Guatemala's overall consumption. Only 18 percent of all 25 - 29 year olds

have graduated from secondary school, representing only half of the Central American average.[136]

More than half of the population is below the national poverty line and 23% of the population live in extreme poverty.[134] The poverty rate (according to the US$4 per day poverty line) increased from 55 percent in 2000 to 60 percent in 2014. This implies that the number of people who live below the poverty line increased from 6.8 million to 9.6 million people during those 15 years. This trend is in striking contrast with the overall decline in poverty in both Latin America as a whole and most of Central America.[136]

Guatemala is heavily burdened by communicable, maternal, neonatal and nutritional diseases. Nearly one-half of Guatemala's children under age five are chronically malnourished, representing one of the highest malnutrition rates in the world.[134] Cardiovascular and respiratory conditions are ranked as the top causes of death in Guatemala. Over 12% of total deaths are attributed to violence, the second highest rating in the world. There is also an increasing magnitude of mental health disorders and a high rate of suicide.[76] Consequently, life expectancy is amongst the lowest in Central America and the Caribbean region at 72 years.[137]

Access to healthcare in Guatemala is challenging and variable. Health expenditure represented as a total percentage of GDP (2014) is 6.2% as compared with the UK and Canada at 9.1%.[138] Guatemala has the lowest health worker density in Central America with 12.5 health workers per 10,000 population.[76] This represents only half of the 22.8 per 10,000 population ratio that the WHO recommends as the minimum for a functioning health system.[76]

The number of physicians per 1000 people in 2009 was 0.9.[139] Accessibility to health workers is more than eight times greater for patients in urban areas than in rural areas, demonstrating inequalities in health service accessibility.[76] The prevalence of disabling hearing loss for Latin America and the Caribbean region, per 100 population is estimated between 4.42 – 6.13%, but these estimates are based on few studies conducted in the region.[140] The availability of information about the prevalence and incidence of hearing impairment in specific Latin American countries remains very limited.[141]

In 2016, the International Centre for Evidence in Disability conducted a large national survey of disability in Guatemala, involving over 13,000 people.[142] The survey comprised of a questionnaire and health screening. The results indicated a 10% overall prevalence of disability with a prevalence of hearing impairment estimated at 4%. This national survey demonstrated that disability prevalence increased by age and was 24% among adults aged over 50 years. The prevalence of disability was higher for women compared to men amongst adults, but not amongst children. In adults, 4% of the population had hearing loss as measured by functional limitation and clinical impairment screening, with higher prevalence in males (4.3%) compared with (3.7%) females.[142] By functional domain, the prevalence of other significant limitations among adults was highest in the domains of anxiety/depression, mobility and vision. Amongst children, the domains with highest reported significant limitations were anxiety, mobility and maintaining relationships.

The study also compared socio-economic characteristics and levels of participation between people with and without disabilities (including people with hearing loss). Nearly one third of the 3095 households in the survey included at least one household member with a disability. These households were significantly more likely to be in the lowest socio-economic status group, had larger household size, higher dependency ratio and a lower proportion of household members who were working compared to households without a member with a disability.

Adults with disabilities were significantly less likely to have attended school (64%) and were more likely to be illiterate (37%) compared to adults without disabilities (72% and 25% respectively). Adults with disabilities were significantly less likely to have worked in the previous week (23%) compared to adults without disabilities (47%). Adults with disabilities had less stable livelihood opportunities: they were significantly more likely to report working only occasionally (30%) compared to people without disabilities (19%).

Among adults with disabilities, the likelihood of work was significantly lower among: Older adults (>50 years), females compared to males, people who had

never married/lived with a partner, People with significant physical functional limitations.

Overall, people with disabilities reported a high degree of environmental barriers across different environmental domains (such as transport, the natural environment and availability and accessibility of services) and across each age group and people reporting significant limitations with physical, cognitive, anxiety/depression, communication, and multiple domains reported worse quality of life compared to people without significant limitations in the corresponding domains/group. No further reliably sourced data regarding the epidemiology of hearing loss in Guatemala has been identified.[141]

In summary, Guatemala is relatively poor as compared with other Latin American countries. Furthermore, the prevalence of disability is high and has a profound impact on people's poverty level, functional activity and participation. It was from this setting that the impact of hearing loss and provision of hearing aids on an adult population was explored.

2. Methodology

2.1 Conceptual Framework

This research project aims to assess the impact of hearing loss and the provision of hearing aids on adults living in Guatemala. This chapter provides a systematic and detailed account of how the study was planned and implemented.

The conceptual framework for the identification of potential areas of impact was based on the WHO International Classification of Functioning Framework, incorporating the key domains of activity, participation, environment and personal factors, within two experience states, hearing loss and hearing aid use. (Figure 7) This formed a conceptual matrix which guided question formulation for both the quantitative and qualitative components of the study and provided the result presentation structure and format. For example, activities of daily living were explored with respect to hearing loss (A1) and with hearing aid use. (A2) Personal factors, such as mental health, the presence of comorbidities as well as social and family dynamics were identified and explored within each of the two states. (D1 & D2) During the post-intervention experience state, specific activities relating to the audiology clinic experience, hearing aid fitting process, device usage, care and maintenance were also examined. (A2)

Theory of Change (ToC) is concerned with how and why an initiative works and may be used to describe how activities and / or an intervention may affect change and lead to interim and long-term outcomes and impacts.[143] The application of a Theory of Change model has multiple uses and roles, such as a management planning and development tool, a guide to resource allocation or service evaluation and a method of communication.[144]

Figure 7: Conceptual Matrix

		Experience State	
		(1) Hearing Loss	**(2) Hearing Aid Use**
ICF Domain	**(A) Activity**	Communication Home Tasks Activities of Daily Living & Self-Care	Communication Home Tasks Activities of Daily Living & Self-Care Clinic Experience & Fitting Process Device Usage Hearing Aid Care & Maintenance
	(B) Participation	Social Relationships & Interactions Employment & Work Social Visits & Meetings Community Involvement Hobbies & Interests	Social Relationships & Interactions Social Visits & Meetings Community Involvement Hobbies & Interests
	(C) Environment	Social Network Safety & Security	External Factors: Background Noise Climate, Humidity & Temperature
	(D) Personal Factors	Mental Health Quality of Life Family & Social Situation Medical History	Mental Health Quality of Life Family & Social Situation

The Theory of Change framework consists of several key elements. The 'impact' is the real-world change or ultimate outcome that one is trying to affect and 'short-long term outcomes' are the intermediary goals that the intervention is able to influence. Contextual factors may influence the Theory of Change and 'assumptions' are external conditions beyond the control of the project that must exist for the outcomes to be achieved.[145] The intervention are the strategies employed to achieve the impact.[146] Figure 8 articulates the Theory of Change model for this research project.

Figure 8: Research Project Theory of Change

Baseline State	Preliminary Activities	Intervention Activities	Short-Term Outcomes	Mid-Term Outcomes	Long-Term Impact
	Ear Health Screening	Ear Mold Production	Improved: Communication & Social Engagement	Improved: Quality of Life	Improved: Quality of Life
	Case Identification	Hearing Aid Fitting		Social Interaction & Relationships	Education
	Hearing Assessment	Hearing Aid Usage		Mental Health	Employment
		Device Maintenance & Usage Review		Activity Participation	Socio-Economic Status & Poverty

The Theory of Change for this research study is based on an adult population with disabling hearing loss (as defined by the WHO) and identified as the baseline state. The preliminary activities contribute to the identification and assessment of hearing loss to determine eligibility for research study participation. The intervention requires the production of an ear mold and fitting of hearing aids, prior to usage and post-intervention, ongoing review and maintenance.

The sequential outcomes are based on literature-generated expectation and divided into short, mid and long term. These represent time frames broadly equating to three months, six months and one or more years.

The short term outcome is to improve communication and increase social engagement. The mid-term outcome is enabling communications to positively influence relationships with family and community, improve social interaction enabling activity involvement and participation and having a positive effect on mental health, such as building confidence and wellbeing.

The long term outcome and impact is to improve access and performance at work and provide educational opportunities, thereby enabling increased income, improvement in socio-economic status and a reduction in poverty. For example,

financial affordability to improve housing conditions, access to health services and improve quality of life. It is acknowledged that quality of life and mental health changes will occur across outcome periods.

The contextual factors for the outcomes include, the severity of hearing loss, age of participants (retirement) presence of comorbidities and other disabling conditions and the broader, environmental conditions of Guatemala, such as political and economic stability or the presence of natural disaster. This Theory of Change guided the selection of the study methods, including the outcomes to be evaluated.

2.2 Study Design

Assessment of impact of an intervention is conventionally undertaken through a randomised-controlled trial or a non-randomized design. Randomised-controlled trials (RCT) are experimental studies in which the impact of intervention is investigated by comparing one subject group who were randomly allocated to receive the intervention with a control group who do not, and receive either a placebo, usual care, or a delayed intervention. A randomised controlled trial is considered to provide the strongest empirical evidence of a treatment or intervention efficacy.[147] Although these studies are designed to minimise bias and have the ability to make causal inferences, ethical concerns relating to the intervention being withheld from the control group meant that a randomised control trial design could not be applied to this research project.

In contrast, a controlled before-after intervention study (a non-randomised design) was chosen as it was ethically appropriate to provide the intervention (hearing aids) to all eligible subjects. The primary outcomes were the change in quality of life, poverty, activities and mental health after receipt of the hearing aid, in comparison to the baseline measures. Comparison subjects without disabling hearing loss were selected from the community, matched by age and gender to each case, to assess whether there were secular changes in these variables during the follow-up period. Every attempt was made to minimise the biases that

could occur during the study (as outlined below) and multivariable analyses were undertaken to adjust for potential confounders.

2.3 Study Overview

A non-randomised controlled study was conducted to assess the impact of hearing loss and provision of hearing aids on poverty, mental health, quality of life and activity/participation on an adult population in Guatemala. Adults with a disabling hearing impairment were identified during a community-based screening exercise and for each case, a matched age and gender control was selected and screened to ensure that they did not have disabling hearing loss. All cases and controls were interviewed using a structured questionnaire which explored quality of life, mental health, activity participation and their socio-economic status. Cases with hearing loss were provided with hearing aids. Following a varied period of six to nine months, cases and controls were re-interviewed to assess the impact of this intervention. In-depth qualitative interviews were conducted to complement the data gathered from the questionnaire. A time-scaled project plan is shown in Appendix 4.

2.4 Research Study Preparation and Management

2.4.1 Project Funding

This research project was funded by World Wide Hearing Foundation International, a non-profit organisation based in Canada.

2.4.2 Project Organisation

This research project was managed by a Primary Researcher and Doctor of Public Health Candidate (Mark Spreckley), based at the International Centre for Evidence in Disability, part of the London School of Hygiene & Tropical Medicine. A Research Supervisor and an Advisory Committee provided ongoing professional & technical guidance & support. In Guatemala, collaborative partnerships were formed with two charitable organisations. These relationships facilitated effective project management and aided logistical organisation.

The key internal project stakeholders and their specific roles and responsibilities are identified and mapped in Appendix 3.

The Sonrisas que Escuchan Foundation is a social outreach programme funded and managed by the Centre of Hearing and Phonetic Training based in Guatemala City. The team of audiologists and technicians fulfilled a critical role in auditory screening and identifying eligible cases for the study. The foundation also fitted the hearing aids and provided ongoing aural rehabilitation and device maintenance.

A collaborative partnership was also established with a Guatemalan Deaf-Blind School, known as FUNDAL, to support administrative and financial management project functions.

2.4.3 Fieldwork Research Team

The full-time research team was comprised of eight team members with the following key roles and responsibilities:

- Research Interviewers (6 FTE): The key role and responsibilities of the Research Interviewer was to travel to participant homes and conduct face to face participant interviews using a pre-designed structured questionnaire. The interview team were expected to collect and collate the research data, ensuring interview responses were accurately recorded and securely stored.
- Lead Interviewer (1 FTE): The Lead Interviewer coordinated the team workload, responded to logistical questions and queries and monitored and managed team performance. The Lead Interviewer was a competent Spanish-English document translator and language interpreter.
- Project Manager (1 FTE): In Guatemala, the Doctor of Public Health Candidate (Mark Spreckley) was the Project Manager, responsible for fieldworker training, performance and data integrity, resource usage and management, project logistics and effective stakeholder relationships, communication and progress reporting.

The six Research Interviewers were paired and divided into three sub-teams. This arrangement addressed safety and security transportation concerns and facilitated effective data collection. Work assignment, performance management and ongoing support and guidance was provided by the Lead Researcher and Project Manager.

2.4.4 Fieldwork Training

In September 2015, prior to the commencement of the pre-intervention phase of the fieldwork, the research team participated in a modular training and development programme. The aim of this event was to provide a robust and comprehensive training programme that prepared each participant for their role and to attempt to maximise quality and minimise bias during data collection. This role included being able to coordinate and conduct effective research interviews, perform auditory screening tests and competently collect and manage research data. Based upon the planned learning outcomes and successful completion of the programme, participants were expected to understand and fulfil the following competencies:

- Define hearing loss, describe the main causes and understand its impact
- Understand the role of the multidisciplinary, clinical audiology team as well as the purpose and format of a hearing assessment
- Appreciate the function, structure, key components and different types of hearing aid
- Understand the basic device maintenance requirements & trouble-shooting techniques
- Understand the objectives of the research project and the purpose of their role
- Interpret the questionnaire structure and content
- Coordinate and schedule research interviews
- Manage an effective interview ensuring that responses are accurately recorded and securely stored electronically
- Effectively communicate with participants and their family

- Conduct all work with professional and ethical integrity, maintaining own safety and participant privacy and confidentiality

The five-day programme was coordinated and delivered by the Project Manager. Specialist lectures on hearing loss and aural rehabilitation were provided by an Audiologist from the Sonrisas que Escuchan Foundation and electronic tablet use was facilitated by an Information Technology Lead from World Wide Hearing Foundation International. The programme was comprised of lectures, workshops, practical exercises and a competency assessment.

During the baseline and follow-up fieldwork, on three separate occasions, two additional and one replacement fieldworker joined the research team. Each fieldworker attended an intensive training programme delivered by the Project Manager and Lead Interviewer. The training incorporated the same teaching components and materials as the team-based, five-day training programme however these elements were condensed and delivered as a series of individual tutorials, practice workshops and assessment scenarios. On day two of the programme each new fieldworker shadowed an experienced two-person research team, observing case and control interviews and their supporting activities. Following the completion of these training activities each new-starter was paired with an experienced research fieldworker who provided ongoing mentorship. Interview performance outcomes were monitored remotely by the Project Manager and additional support and guidance was provided during regular field visits and team meetings.

2.4.5 Project Risk Management

At each stage of the project planning and implementation process, performance and activity outcomes were closely monitored and reviewed. Planned performance was measured against actual performance delivery. During the fieldwork, operational and logistical challenges were identified, and a hierarchy of risk management strategies employed. These are described and reviewed in the discussion chapter. Project updates and fieldwork progress reports were regularly generated by the Project Manager and provided to the key project stakeholders, including the Research Advisory Committee and project sponsors.

2.5 Study Methods

2.5.1 Case Sample Size Calculation and Justification

This research project aimed to identify 200 cases and 200 controls. This sample size was appropriate for the following comparisons:

- At Baseline to detect an odds ratio of 1.85 comparing cases and controls for the association between poverty and hearing impairment, assuming that 25% of controls are in the poorest quartile, with 80% power and 95% confidence.
- To detect a 30% change in quality of life associated with hearing aid use to be detected, with 80% power and 95% confidence (factoring in loss to follow-up and non-compliance with hearing aid, so that 100 cases were available at both time points).

The two hundred cases to be included in this research project were selected based on methods and eligibility criteria described below.

2.5.2 Sampling, Case & Control Selection

Two hundred adult cases with disabling hearing loss were identified through the community outreach screening activities of the Sonrisas que Escuchan Foundation, based in Guatemala City. This identification process was undertaken in 2015, over a six-month period of community outreach ear-health screening. Depending on the geographical location, the venue for the screening clinic included a church hall or community school building.

The community-based screening programme sought to identify individuals with hearing loss and is the prerequisite for any further hearing health measures, treatment or rehabilitation.

The protocol for adult case hearing screening included the following key components:

- **Case History:** Each participant is formally identified, and a review of chronic diseases, medications and family history is recorded
- **Otoscopic Inspection:** A visual inspection of the ear was carried out to identify any obvious anatomical abnormalities or blockages caused by impacted ear wax, foreign bodies, infection or fluid.
- Pure-tone Conduction Hearing Test
- **Referral** for a comprehensive audiological evaluation or ear wax impaction removal procedure

Hearing loss was confirmed by pure-tone audiological tests which were performed in a designated room within the community setting, using calibrated, portable equipment and by a qualified and experienced Audiologist. Using the World Health Organisation classification of hearing loss, adults and children with thresholds between 0 and 25 dB, across all frequencies are considered to have 'normal' hearing.[20] The detection of disabling hearing loss is classified as greater than 40 dB in the better hearing ear in adults (15 years or older) and greater than 30 dB in the better hearing ear in children (0 to 14 years).[21] People were eligible for inclusion if their bilateral hearing loss was classified as moderate - profound. A decision on referral for hearing aids was made by the audiologist based on the hearing test results and consideration of diagnostic and wider social and health factors which may contraindicate their use.

All potential cases were interviewed by the Sonrisas que Escuchan Foundation Executive Director to assess whether they reported that they were independently unable to finance and access aural rehabilitation services. Based on this interview and at the discretion of the Clinical Director, potential cases were determined eligible for subsidised hearing aid provision at $50. At this time, these participants were invited to participate in the study. There was a variable delay period between case screening and identification and their participation in the research study of between one week and up to six months.

Further restrictions on eligibility were also implemented. The Theory of Change was formulated for adults, and different pathways and impacts would be operational for children. Consequently, the study was restricted to adults, aged 15 years or above. Furthermore, participants were restricted to those who lived within 150 km of Guatemala City. The size of the geographical area was determined by the Sonrisas que Escuchan Foundation screening programme coverage, based on resource and transportation capacity. A summary of the case inclusion criteria is identified in Table 9.

Inclusion criteria for the controls (in addition to the matching variables of age, gender and location) were that they were unrelated to the case, (i.e. were not family related to the case such as a parent or sibling) and did not have disabling hearing loss. To verify the absence of disabling hearing loss, all potential controls underwent an auditory screening test using a portable, electronic tablet-enabled audiometer known as the 'Shoe-Box Application' prior to being interviewed. The test was conducted in the controls home, by a trained fieldworker and was used to ensure that participants who presented with disabling hearing loss (measured as 41 dB and above) were excluded from the control group and offered a referral and follow-up assessment at the Sonrisas que Escuchan Foundation. The presence of disabling hearing loss excluded the controls from participating in the research.

To identify a matched control group, each case was requested to identify three non-related neighbours within the same geographical area, in close proximity to their own home, that is, within walking distance to the adjacent house or within the same street. The names, address and telephone number was recorded by the fieldworker. Based on a random selection process, out of the three individuals identified, one was randomly selected, contacted and invited to participate in the study. If he/she declined or was not eligible, then a second control was randomly selected (and if need, the third). Interviews with controls were undertaken at a pre-arranged time and were conducted within their own home. This selection method was used as it was a convenient and efficient way to identify a matched control group. Controls were from the same location and lived within similar environmental conditions, thereby contributing to the control of such confounding

variables as well as increasing the likelihood of voluntary research participation because the case is known to the potential control or/and is part of the same community.

Table 9: Summary of Case Inclusion Criteria

Parameter	Case Criteria	Comment
Sex	Male or Female	Aged 15 Years +
Age	Adult	
Hearing Test Outcome	Bilateral Hearing Loss: ▪ Moderate ▪ Severe ▪ Profound	WHO Classification of Hearing Loss
Socio-Economic Status	Unable to independently afford to purchase hearing aids	Self-Reported
Geographical Location	150 Kilometre radius of Guatemala City	Uban and rural areas

2.6 Data Collection

All cases and controls were interviewed at baseline and follow-up using a structured questionnaire by a pair of trained fieldworkers, in their own home at a pre-scheduled appointment time. The purpose and format of the interview was explained to the subject. The subject was also asked to read or listen to explanatory research study information prior to signing or providing their thumb-print to consent their participation.

The standardised questions were verbally administrated in Spanish, in a pre-determined format using the electronic tablet and a hard, back-up copy reference document. Upon completion of the interview, the clinic was notified that the questionnaire had been administered and a hearing aid fitting appointment was scheduled and the case notified of the date and time.

2.6.1 Questionnaire Development

The production of the baseline and follow up questionnaire involved several key developmental stages.

Initially, a scoping of the literature was carried out to identify the domains for the questionnaire and to determine the appropriate assessment tools.

A preliminary draft version of the questionnaire was reviewed and scrutinised by three members of the Research Advisory Committee as well as two representatives from World Wide Hearing. This review identified specific grammar, structural and content errors which were addressed prior to the commencement of the pilot testing phase. Data coding and scoring mechanisms were also confirmed.

Pilot testing of the pre-and post-intervention questionnaire was undertaken in the UK and Guatemala. In the UK this involved the Project Manager interviewing two people, of similar profile to the case and control group, i.e. older adults, to determine the optimal sequencing of questions, ensure content understanding and confirm the interview duration. Following this exercise the questionnaire content was clarified and updated.

The pre-and post-intervention questionnaire were compiled and translated into Spanish by an experienced Project Translator from Guatemala and independently back-translated by an English-Spanish Language Teacher from Guatemala. Any cultural interpretation discrepancies were addressed. During a preliminary planning trip to Guatemala, the questionnaire was pilot tested on three case-profiled participants, identified by the Sonrisas que Escuchan Foundation. These interviews were conducted in the participants home, by the Audiologist and Director of the Sonrisas que Escuchan Foundation in Spanish and were observed and assessed by the Project Manager. Following this exercise elements of the question content and structure were further refined.

The questionnaire was formatted and displayed using the 'KoBo Toolbox' application. This is a free open-source tool for mobile data collection which enables data to be collected in the field and supports the full data collection cycle from questionnaire design, data collection and analysis.[148] The KoBo Toolbox is predominantly used for data collection activities within challenging field

environments, such as emergency humanitarian work. The usability of the tool was tested through paired team members interviewing each other using the electronic version of the questionnaire. Where necessary, revisions were made to the formatting, skip-logic and sentence structure of the questionnaire.

2.6.2 Questionnaire Structure & Content

The questionnaire (See Appendix 5) was comprised of twelve distinct sections and each part was based on a specific question theme, as identified in Figure 10. Questions relating to 'Hearing' (Part I & II) and 'Significant Other' were not applied to the control group. The interview commenced with verification of subject identity and demographics, including name, age, date of birth and home address. The baseline questionnaire consisted of 155 closed-questions for cases and 102 for controls.

Figure 10: Baseline Questionnaire Structure

Section	Questionnaire Sections	Case Group	Control Group
Introduction	Subject Identity & Demographics	☑	☑
Part I	Hearing I	☑	
Part 2	Household	☑	☑
Part 3	Home	☑	☑
Part 4	Activities & Work Participation	☑	☑
Part 5	Income	☑	☑
Part 6	Expenditure & Consumption	☑	☑
Part 7	General Health	☑	☑
Part 8	Mental Health	☑	☑
Part 9	Quality of Life	☑	☑
Part 10	Hearing II	☑	
Part 11	Significant Other Question Set	☑	

Part 1: Hearing

This preliminary set of four case-specific questions relates to hearing loss onset and previous health-seeking behaviours and sources.

Part 2: Household Composition

This question set aimed to determine the composition of the household. Household members were defined as all adults and children that have lived in the household for at least six months of last year, eat meals together, do not pay rent

and are not classified as domestic help. Marital status, literacy and education were also recorded.

Part 3: Home Characteristics and Asset Ownership

This question set related to the properties of the home or household dwelling, including its structure, composition, lay-out, sanitation, fuel and utility sources and land ownership. The respondent was also asked to specify the number and type of context-specific, fully working assets owned by the household from a pre-determined list. This included, furniture items, electrical equipment and modes of transport.

Part 4: Activities & Work Participation

Activity data was collected using an adapted activity list developed for the World Bank's Living Standards Measurement Survey.[139,149] Participants were asked whether they had been involved in a list of common daily activities during the last week and if they had, whether they had been involved in that activity yesterday and to estimate how much time they had spent on each activity, recorded as minutes and hours. Figure 11 describes how each of the activities were grouped. This was followed by ten specific questions relating to the classification, frequency and working conditions of employment. This question set was adapted from a Household Survey Module.[150]

Figure 11: Activity-Time Categories

Activity	Example
Household Tasks	Cooking, washing dishes, shopping
Employment	Paid or self-employed
Household Work	Own farming and childcare
Social Visits	Visiting friends and family, celebrations or church
Leisure Activities	Reading, watching TV, entertaining
Daytime Sleeping	Daytime nap or rest
Other Activity	Excluded from above list

To capture the complexities of poverty, sections 5-6 of the questionnaire applied a multi-dimensional approach to poverty measurement.[151] The questions were adapted for use in Guatemala from the survey prepared by the Multidimensional Poverty Peer Network (MPPN) & Oxford Poverty and Human Development Initiative[150] The key elements of deprivation such as poor health, lack of education, inadequate living standards, amenities and poor quality of work were addressed by applying the following question sets.

Part 5: Income:

This question set consisted of three questions relating to weekly or monthly personal income, total household income and the identification of other sources of income, such as a pension, a secondary job or financial support.

Part 6: Household Expenditure

A measure of per capita and household expenditure was calculated as a proxy measure for income. Expenditure (per capita) was measured using methods based on the World Bank's Living Standards Measurement Survey. [139,149] During the pilot testing phase, a list of items were reviewed and selected for cultural relevance. The list included 70 items, including, food, beverages, clothing, household utility bills, taxes, education and healthcare costs.
For each item, participants were asked about the quantity and value of the product or services used, and whether they were they purchased, gifted, a payment in kind or home produced. Consumption was asked over a recall period of one week, for frequently bought items and within the last month, for less frequently bought items. For each item a financial value in local currency (GTQ) was assigned, and its origin recorded.

For example, over the past week has your household eaten any of the following food items? Butter, beans, milk or tortilla?

Over the past month has your household spent any money on any of the following household items? Kitchen equipment, furniture and home maintenance and repair?

Figure 12: Summary of Socio-Economic Status & Poverty Measures

Element	Example
Income	What are the total monthly household earnings?
Expenditure	What does the household spend on a monthly basis?
Ownership of Assets	Car, refrigerator, radio and television
Housing Characteristics	Number of rooms and material of the dwelling floor and roof
Access to Basic Utility Services	Electricity supply, source of drinking water and sanitation facilities
Education & Work	Level of education, the nature and description of work, job number, frequency, duration, hours, pay and benefits

Part 7: General Functioning

Functional status was assessed through the Washington Group Short Set questionnaire.[152] This short version of the questionnaire consists of six questions and assesses activities of daily living and the core universal elements of sensory function, cognition and mobility. The question format 'Do you have difficulty with …' applied a four-point response scale, ranging from 'No Difficulty, 'Some Difficulty', 'Lots of Difficulty' to 'Unable to Perform' The responses were coded for level of difficulty and functional measure and summed.

Part 8: Mental Health

Depressive symptoms were assessed using the Patient Health Questionnaire, which is a validated mental health screening tool.[153] The PHQ-9 is a multipurpose, self-reporting instrument for screening, diagnosing, monitoring and

measuring the severity of depression. The PHQ-9 screens and assigns weight to the degree to which depressive symptoms have affected the patient's level of function. Question nine screens for the presence of suicide ideation. The tool rates the frequency of the symptoms which factors into the scoring severity index. Each participant was asked the first two questions, and if they scored positively for depression, the remaining seven questions were administered.

The final question asks the patient to report on 'How difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?' This question represents the respondent's global impression of symptom-related impairment and is not used in calculating the PHQ score. It may be useful in decisions regarding initiation of, or adjustments to treatment as it is strongly associated with both symptom severity as well as multiple measures of impairment and health-related quality of life.[154] The question relating to suicide risk was sensitively administrated and any concerns relating to case or control health and safety were reported to the Audiology Clinic. Under these circumstances, follow-up guidance and support was offered to the participant.[154,155]

Part 9: Quality of Life

Quality of life is defined as an individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.[156] Quality of Life relates to a person's subjective well-being and is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to their environment.[157]

Quality of life was measured using the WHOQOL-BREF, which includes twenty-six questions divided into four domains.[158] The domains include, physical health, psychological health, social relationships and the environment. The WHOQOL-BREF is a person-centred, multilingual instrument for subjective assessment of well-being and is designed for generic use as a multi-dimensional profile, so enabling a wide range of diseases and conditions to be compared. The question set can be used in situations where time is restricted, where respondent burden

must be minimised and where further detail is unnecessary. The questionnaire has good psychometric properties.[157] The key elements incorporated in the four domains include:[159]

Physical Health: Activities of daily living, dependence on medicinal substances and medical aids, energy and fatigue, mobility, pain and discomfort, sleep and rest and work capacity.

Psychological: Body image and appearance, negative and positive feelings, self-esteem, spirituality/religion/personal beliefs, thinking, learning, memory and concentration.

Social Relationships: Personal relationships, social support and sexual activity.

Environment: Financial resources, freedom, physical safety and security, health and social care: accessibility and quality. Home environment, opportunities for acquiring new information and skills, participation in and opportunities for recreation/leisure activities. Physical environment (pollution/noise/traffic/climate) and transport.

Part 10: Hearing (Part II)

The Hearing Handicap Inventory for Adults: (HHIA) This is a 25-item, self-assessment questionnaire designed to measure the emotional, social and situational impact of hearing loss.[160] The HHIA represents a revised and updated version of an inventory for older persons which was first developed in 1986.[160] The use of terminology such as ‘handicap’ is inappropriate and stigmatizing and has been substituted for the word ‘disability’ by the author for this current study. The HHIA applies a three-point response scale, enabling the participant to answer ‘yes’, ‘no’, or ‘sometimes’ to each question.[161]
These responses are numerically coded and summed to produce a total score. The higher the score, the greater the difficulties experienced by the person with hearing impairment.

High levels of reliability and validity have been reported with the use of the HHIA instrument with face-to-face interview being more reliable than written test administration.[103]

The Self-Assessment of Communication (SAC) and Significant Other Assessment of Communication: (SOAC) These questionnaires are based on nine questions focusing on the experience of communication, emotional impact and quality of life.[162]

For example, do you experience communication difficulties when watching television or listening to the radio? A tenth question was adapted by the author and specifically relates to personal safety and security attributed to hearing loss. For each question, there is an adapted 10-point response scale ranging from 1 = 'Never' 5 = 'Sometimes' and 10 = 'Always'

These numerical responses (Q1-9) were summed to produce a total score for each case participant. The scoring classification is divided into four categories: (0-20) no disability/handicap, (21-40) slight disability/handicap, (41-70) mild-to-moderate disability/handicap, and (71-100) severe hearing.[163]

Part 11: The Significant Other Assessment of Communication (SOAC)

This is a self-report questionnaire designed to measure the effect of hearing loss and the impact of hearing aids as assessed by a known third party.[162,164] For example, does he/she experience communication difficulties in situations when conversing with a small group of several persons? How often does hearing loss negatively affect his/her enjoyment of life?

These questions are similar to the Self-Assessment of Communication instrument, however are designed to be completed by a 'Significant Other'. This is defined as a close family member of the person with a hearing impairment, who lives within the same household such as, a wife, partner or husband.

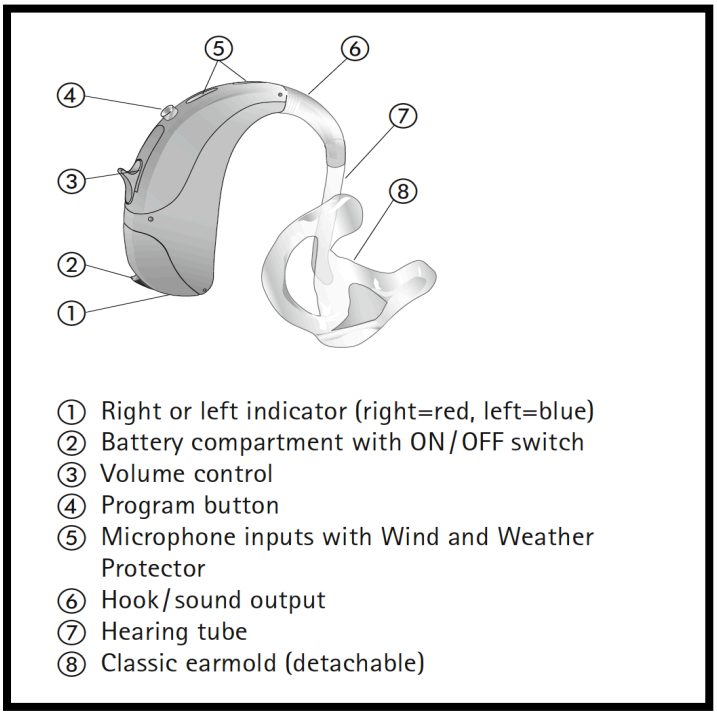
During the concluding stages of the baseline interview with the case, a significant other was identified. Within the same room and in the presence of the case, the identified household member provided verbal consent and was asked to respond to the ten questions.[163] The same, identified significant person participated at both baseline and follow-up. For each question, an adapted 10-point response

scale ranging from 1 = ‘Never’ 5 = ‘Sometimes’ and 10 = ‘Always’ was applied. These numerical responses were summed to produce a total score for each participant.

2.7 Hearing Aid Intervention

Once the baseline interview had been completed all case participants were contacted by the Sonrisas que Escuchan Foundation and invited to visit the clinic to have their hearing aids fitted. A total of 376 hearing aids were purchased and fitted. The brand-new, behind the ear devices were manufactured by Phonak (Baseo Q15 Model) and donated by World Wide Hearing. These standardised, four-channel entry level digital instruments are suitable for mild-profound hearing loss and provide reliable and effective sound quality.[165,166] Hearing aid selection was based on identifying a quality device from a dependable and recognised brand. This standardised model, shown in Figure 13 was consistently fitted on all cases.

Figure 13: Hearing Aid Components[166]



The Sonrisas que Escuchan Foundation charged each case participant $50 USD, per aid which contributed to the cost of the device, batteries and follow up care. During the fitting appointment, participants were given the necessary supporting equipment and resources, such as a supply of batteries, protective case, de-humidifying dryer as well as ongoing access to maintenance and repair services. Guidance and support in the use and care of their hearing devices was provided verbally. To encourage and support hearing aid usage, participants were contacted regularly and encouraged to make monthly re-visits to the clinic to check the functionality of their devices. During this visit, operational hearing aid usage data was captured, battery supplies replenished and a hearing aid inspection conducted.

2.8 Follow-up

The period of time allocated for hearing aid ownership and potential usage varied amongst cases from six-nine months depending on their fitting date and their availability to be re-interviewed. Due to research funding completion deadlines a longer period of hearing aid usage was not feasible. In July & August 2016 all case and control participants were contacted, appointments scheduled and they were re-visited in their homes and a post-intervention interview and structured questionnaire was completed.

The questionnaire that was delivered at baseline was adapted to be administered at follow-up. This included the addition of three question sets specifically relating to hearing aid usage and experience (described below). The interview commenced with re-verification of subject identity and demographics, including name, age, date of birth and home address.
The follow-up questionnaire consisted of 180 closed-questions for cases and 93 for controls. (See Appendix 6) The structure and content of the post-intervention questionnaire is described in Figure 14.

Figure 14: Post-Intervention Questionnaire Structure & Content

Section	Questionnaire Question Sections	Case Group	Control Group
Part 01	Subject Identity & Demographic Information	☑	☑
Part 02	Household	☑	☑
Part 03	Activities & Work Participation	☑	☑
Part 04	Income	☑	☑
Part 05	Expenditure & Consumption	☑	☑
Part 06	General Health	☑	☑
Part 07	Mental Health	☑	☑
Part 08	Quality of Life	☑	☑
Part 09	Hearing (A-F)	☑	
Part 10	Significant Other Question Set	☑	

Part 9 of the follow-up questionnaire relates to hearing and captures the following, additional hearing aid experience and usage question sets:

International Outcome Inventory - Hearing Aids (IOI-HA)

The International Outcome Inventory for Hearing Aids (IOI-HA) is an instrument designed to evaluate the effectiveness of hearing aid use, assessing benefit, satisfaction and quality-of-life changes.[161] The IOI-HA is comprised of seven questions which represent specific outcome domains including, hearing aid usage, benefit, residual limitation, satisfaction, participation, impact of others and quality of life. The participant is presented with a variable, five-point rating scale for each of the seven questions, with higher scores representing better outcomes.

Satisfaction with Amplification in Daily Life (SADL)

This tool is a self-report measure which assesses the multi-dimensional nature of satisfaction with hearing aid use.[167] The instrument consists of 15 questions related to aspects of hearing aid use and provides a global score indicating overall satisfaction. Four sub-scale scores profile satisfaction in the areas of positive effect with improved psycho-acoustic performance and functioning, service and cost, based on value for money, product dependability and confidence in the clinic provider and personal image, including appearance. The undesirable effects of hearing aid use are captured as negative features and include background noise and feedback.[168,167,169.] Respondents are required to indicate their level of satisfaction on a scale of A-G, 'A' representing 'Not at all' and 'G', 'tremendously.'[170]

Hearing Aid Satisfaction

A set of twelve questions were used to explore satisfaction with hearing aid usage. This included, device features, most significant benefits and safety and security concerns. The questions used a five-point satisfaction rating, ranging from 'Very Dissatisfied' – 'Very Satisfied'. A final question asked about the most significant benefit of using hearing aids and provided a six-point response option, based on activity participation and social interaction, such as communication with friends and family, watching TV and listening to music or able to work and earn money.

2.9 Data Entry

At baseline and follow-up, the participant responses were recorded and saved on a hand-held, electronic, android tablet. The key features of this data presentation and entry method was as follows:[171,172]

- Device portability and large data storage capacity
- Password protected access and enhanced data security
- Avoidance of time-consuming and error-prone double manual data-entry
- Touchscreen data entry and skip-logic, saved time and ensured data entry accuracy and completeness.
- The tablet did not enable incomplete questionnaires to be saved or uploaded, thereby prompting correction
- Missing data could be easily re-traced and re-entered thus reducing the amount of data cleaning required.

In practice, questions that required numerical calculation (e.g. time use) were not auto-summed by the questionnaire format and therefore fieldworkers were provided with template calculation sheets and instructed to use a calculator, recording the data manually and entering post-interview. This process enabled case response verification and calculation accuracy.

The electronic tablet and hearing test equipment, including the iPad and headphones were valuable tools and considered high-status items and a theft risk in Guatemala. Keeping the tablets secure and hidden while walking to interviews or using public transport was a priority for the fieldworkers. Wi-Fi coverage was geographically variable and effective data storage and analysis was dependent on uploading the interview data via the internet to the project server. In case of tablet failure or poor WiFi connection, paper-based versions of the questionnaire were used and data manually entered and later uploaded to the working tablet. The Project Manager (author) was able to review and monitor the uploaded data remotely.

2.10 Data Cleaning

During the pre-and-post intervention data collection periods, the Project Manager was able to remotely access, track and review the project data using the KoBo Toolbox 'Dashboard'. This interface enabled 'live' data collection progress, performance and data integrity to be monitored:

Key activities included:

- Confirming data receipt and rectifying data-uploading failures
- Clarifying case identification and cross-referencing with clinic lists to ensure inclusion and appropriate interview timetabling
- Detecting numerical input errors and providing correction
- Removing duplicated or test-bed data inputs
- Progress and performance information was shared with the Fieldworker Team and where appropriate, constructive feedback or remedial actions were provided during team meetings. This included actions such as, performance updates, data handling techniques and technical trouble-shooting.

2.11 Quantitative Data Analysis

The data analysis plan was developed by the author and the statistical analysis was undertaken by a statistician from the London School of Hygiene & Tropical Medicine, with direction and discussion by the author. The questionnaire data was downloaded from the 'KoBox' dashboard in a Microsoft Excel spreadsheet format. Spreadsheet I contained the baseline data and spreadsheet II the follow-up data.

The data was then cleaned, this included confirming the inclusion criteria and removing all cases with unilateral hearing loss (and therefore not classified as disabling hearing loss) and response outliers. All data analyses were restricted to participants (cases, controls and significant others) who had both baseline and follow-up data. The following data indicators were generated to measure each subject domain:

Disability: The self-reporting of functional or sensory disabilities as defined by the Washington Group Short Question Set. The value labels used for each of the questions were 1 = 'No difficulty, 2 = Yes - some difficulty, 3 = Yes - a lot of difficulty 4 = Cannot do at all. Each of these descriptors represented a threshold in the determination of a final disability identifier; for example, to define those with and without disability and including and excluding their hearing loss.[173] People were identified as having a disability if they reported having "a lot" or more difficulty in at least one domain.

Activity & Time Use: The mean proportion of time spent on each activity group was calculated by dividing total minutes on specific activity groups by the sum of minutes reported on all activities for that individual. To facilitate interpretation, the proportion of time was converted into hours and minutes.

Asset Ownership: A relative index of household assets was derived using principal components analysis (PCA) to determine weights for a list of specific assets and wealth indicators. Variables entered into the PCA included building materials of the house and ownership of household assets. The derived index was divided into quartiles from poorest (lowest socio-economic status [SES] index) to least poor (highest SES index).

Income: Household income was calculated by identifying the total paid work contribution from household members and other income source disclosures such as, financial support, pension, investments or secondary paid-work sources. From a weekly amount, monthly and total annual household income was calculated in US ($).

Per Capita Expenditure: The consumption on all 70 items was summed to calculate total monthly household consumption, and this was converted from Guatemalan Quetzals (GTQ) to US ($). Per capita expenditure was calculated by dividing total monthly household consumption by the number of household members.

Depressive Symptoms: The severity of depression was calculated by assigning scores ranging from 0 - 3 to the four response categories which ranged from 'Not at all', 'several days', 'more than half the days' and 'nearly every day'. The total possible score for the nine items ranged from 0 - 27. Scores of 5, 10, 15, and 20 represent cut-points for mild, moderate, moderately severe and severe depression, respectively.[174]

Quality of Life: Numerical values were assigned from 1-5 for each of the five response categories. The total scores for each domain (physical health, psychological health, social relationships and environment) were calculated and their sum used to produce an overall quality of life score.

Self-Assessment of Communication and Significant Other Assessment of Communication: The response categories were based on a numerical scoring of 1-10. (1 = 'Never' and 10 = 'always') A total score for each case and significant other was produced.

Hearing Handicap Inventory for Adults: Numerical values were assigned from 0-4 for each of the three response categories (Yes = 4, No = 0 & Sometimes = 2) and a total score for each case produced.

International Outcome Inventory - Hearing Aids (IOI-HA): Numerical values were assigned from 1-5 for each of the five varied response categories and a total score produced.

Satisfaction with Amplification in Daily Life: Respondents indicated their level of satisfaction on a scale of A-G, 'A' representing 'Not at all' and 'G', 'tremendously' The 7-point satisfaction scale was assigned a numerical rating and were summed to provide an overall assessment score.

2.12 Hearing Age Usage

Self-reported hearing aid use and actual usage responses were standardized using a 4-point scale (<1 Hour, 1-4, 4-8, 8-16 hours per day) and each case result populated onto a matrix. Over and under reporting case populations were identified. The Non-Usage Reason category scores were summed and percentage scores across each response category were calculated and presented graphically. Stated 'Other Reasons' were recorded by frequency and presented as case responses.

2.13 Statistical Tests & Data Analysis

Parametric and non-parametric statistical tests were used to compare the cases and controls in the key variables. The significance level or Alpha (α) value for data analysis was 0.05 (5%).

Parametric tests are based on the assumption that data from an underlying population is normally distributed.[175] Key parametric analyses performed were regressions. Regression is used to determine how one set of data relates to another, it quantifies the association and is usually applied if one of the variables is thought to precede or cause the other.[176] Both logistical and linear regression (restricted to two possible outcomes) were applied to this study.

The other parametric tests which were applied to this study included the Analysis of Variance (ANOVA) which measured the Stratified Hearing Handicap Inventory for Adults. The Chi Squared Test is a test of association between two categorical variables and measures the difference between actual and expected frequencies.

Non-Parametric statistical tests do not assume the shape or parameter of the population distribution from which the sample was drawn.[175]

In this research study the Wilcoxon Signed Rank Test was used to analyse individual and household income for cases and controls at baseline and follow up. The McNemar analysis is used to determine if there are any differences on a dichotomous, dependent variable between two related groups. This form of statistical test is commonly employed to analyse matched pairs and case-control studies. The test is based on the assumption that there is one categorical dependent variable with two categories and that the two groups of the dependent variable are mutually exclusive.[177]

2.13.1 Baseline Data Analysis

The socio-demographic characteristics, including living conditions, employment, disability and asset score of cases and controls at baseline were analysed using logistical regression. Odds ratios (OR) were calculated to compare the frequency of characteristics (e.g. age group, gender, marital status) between people with disabling hearing loss (cases) or those without disabling hearing loss (controls). These analyses were adjusted for age and sex using multivariable logistic regression.[178] The 95% confidence interval (CI) was generated to estimate the precision of the Odds Ratio and was presented in the results table.[178,179,180]
A comparison of income for individuals and households between cases and controls was analysed using linear regression and the predictors of annual income in cases was analysed using a Wilcoxon Sign Rank Test.

Total monthly expenditure was compared between cases and controls using linear regression and for quartiles per capital expenditure and per category, logistical regression was applied. Stratified expenditure at baseline for cases was analysed using a Wilcoxon Sign Rank Test. A comparison of case and control activity-time usage was analysed using linear regression.

Depression and depressive symptoms between cases and controls at baseline were compared using logistical regression. A comparison of quality of life between cases and controls at baseline was made using linear regression. The stratified Hearing Handicap Inventory for Adults was analysed using ANOVA analysis and the Self-Assessment of Communication among cases was compared with the Significant Other Assessment of Communication using linear regression.

2.13.2 Follow Up Data Analysis

At follow up, a comparison of employment status at baseline and follow up for cases and controls, separately, was undertaken using a Chi Squared Test. A non-parametric analysis, the Wilcoxon Sign Rank Test was used to compare individual and household income at baseline and follow-up for cases and controls, separately whilst a comparison of monthly expenditure at baseline and

follow up for cases and controls, separately, was analysed using linear regression. A comparison of asset ownership at baseline and follow up for cases and controls, separately, was analysed using logistical regression, whilst a comparison of activities of daily living at baseline and follow up for cases and controls were analysed using linear regression.

For comparison of symptoms of depression at baseline and follow up for cases and controls, a paired and categorical analysis using a McNemars test was employed. The Quality of life scores at baseline and follow up were compared for cases and controls using linear regression. A comparison of Hearing Handicap Inventory for Adults scores at baseline and follow up among cases was analysed using linear regression and their associated assessment outcomes analysed using a Chi Squared Test.

A comparison of Self-Assessment of Communication at baseline and follow up among cases was undertaken using linear regression. The mean scores (overall and for each domain score where relevant) and standard deviation was calculated for the Hearing Handicap Inventory for Adults (HHIA), Self-Assessment of Communication & Significant Other Assessment of Communication.

Methodology: In-Depth Interviews

2.14 Study Purpose

The qualitative phase of the research study aimed to provide an in-depth understanding of the impact of hearing loss and the satisfaction with hearing aid provision. In contrast to the quantitative results which helped to define and determine what the hearing loss and hearing aid impact is, the qualitative data aims to explain why such impacts occur, understanding their complexity, inter-play and situational context.

By exploring the participant's detailed knowledge, experiences, feelings and opinions, this in-depth interview data is used to:

- Assist with interpretation of the quantitative data
- Triangulate the data and assess whether similar findings were obtained through both quantitative and qualitative methods.
- Enable any unanticipated results or topics not covered in the quantitative data to be identified
- Explore the barriers and facilitators to hearing aid uptake
- Assess the relationship between device usage and satisfaction

The epistemological approach used in this qualitative analysis was grounded in Social Representations Theory (SRT). Social representation is defined as;

'The ensemble of thoughts and feelings being expressed in verbal and the overt behaviour of actors which constitutes an object for a social group.'[181]

SRT is primarily concerned with the content of people's thoughts and feelings and the meaning they attach to a specific issue and its consequences. SRT does not focus on the *reality* or the *accuracy* of a representation to the subject matter. The meaning is specific to the individual, their social group or community.[182]

For example, the individual's personal experience of hearing loss is explored rather than an account of hearing loss that is measured against an academic definition and description.

2.15 Participant Sampling Profile

During the follow-up phase of the research project, twenty case participants were selected for in-depth interviews. Cases were selected using purposive, convenience sampling and the following population-based inclusion criteria (Figure 15). The justification for using a sample size of 20 interviews was based on the point at which data saturation is reached. The selection process was undertaken by the author and based on such criteria as ensuring representation of a broad range of case participant characteristics of different ages, both sexes, impairment severity and employment status.

Factors such as voluntary participation, ease of contact, accessibility and location were also considered. All participants were identified as adult cases with a confirmed state of disabling hearing loss at baseline (Moderate-Profound) who had been fitted with hearing aids. Hearing aid usage during the follow-up was not a pre-requisite for inclusion.

Figure 15: In-Depth Interview Inclusion Criteria Summary

Population Criteria	Interview Status Requirement
Participant Status	Identified 'Case'
Participant Characteristics	Adult (male or female and of any age)
Hearing Test Outcome	Disabling hearing loss confirmed
Hearing Aid Provision	Previously fitted through the intervention (Worn or unworn at interview)
Duration of Hearing Aid Ownership	Varied duration (6-9 months)
Post Intervention Questionnaire	Completed

2.16 Framework & Question Set Design

The qualitative interview topic guide was designed to address the key research objectives. The development of a conceptual framework and the Theory of Change, as illustrated in Figure 7 and 8, facilitated the question context, scope and design. During the development process the questions were shared with the Advisory Committee and feedback enabled content specific revisions to be made. Prior to the commencement of the qualitative research process the questions were pilot tested in the field and minor structural order and terminology revisions were made. The final version of the question set and interview schedule, based on this conceptual framework is shown in Appendix 7.

2.17 Data Collection Period

Each in-depth interview was undertaken within a few days following the completion of the post-intervention questionnaire. The qualitative interviews were undertaken in July and August 2016.

2.18 Conduct of Interviews

The qualitative research was undertaken by the author, in English and the Lead Research Fieldworker provided Spanish interpretation. Interviews were designed, and pilot tested to be of a 45-60-minute duration. Interviews were scheduled in advance and participants were invited to select a location, based on their preference, for example, considerations included close proximity to their place of work, childcare arrangements or a limited time period off work. Interviews were conducted either in the case participants home or a convenient and quiet public or community space or meeting room. If public transportation was used to attend the interview, the financial cost of the return fare was reimbursed. Some participants were accompanied by family members or a significant other, whilst others participated independently.

2.19 Interview Schedule

The schedule consisted of an interview format and inclusion criteria checklist followed by a participant identification question set and an observational outcome report. This record captured observational data such as the interview location, presence of background noise, usage of hearing aids and third-party attendance. The schedule incorporated eight question domains which were themed around hearing loss experience, barriers and facilitating factors to uptake and hearing aid impact. Question prompts were used to provide further explanation and elicit detailed responses. These were based on activity, participation, environmental and personal factors. The interview schedule is shown in Appendix 7.

The interview agenda provided a formal structure and the associated activities and sequential stages are shown in Figure 16. Question order and delivery was designed to be flexible and open. Off-script, in-depth and concentrated questioning and responses were actively promoted.

Figure 16: Interview Agenda

Interview Agenda

1. Research Team Introduction
2. Interview Purpose & Objectives
3. Signed Consent: Voluntary Participation & Audio Recording
4. Demographical Checklist: Participant Identity & Observations
5. Question & Answers: Domains 1-8
6. Interview Conclusion
7. Participant Acknowledgement
8. Photograph Request: Verbal Consent Recorded

All questions were delivered in English by the Author (Mark Spreckley) and translated into Spanish by the Interpreter. Responses were provided in Spanish and translated into English. The interview was concluded with an open opportunity for the participant to provide feedback or share any additional information.

2.20 Data Formatting, Information Management & Data Analysis

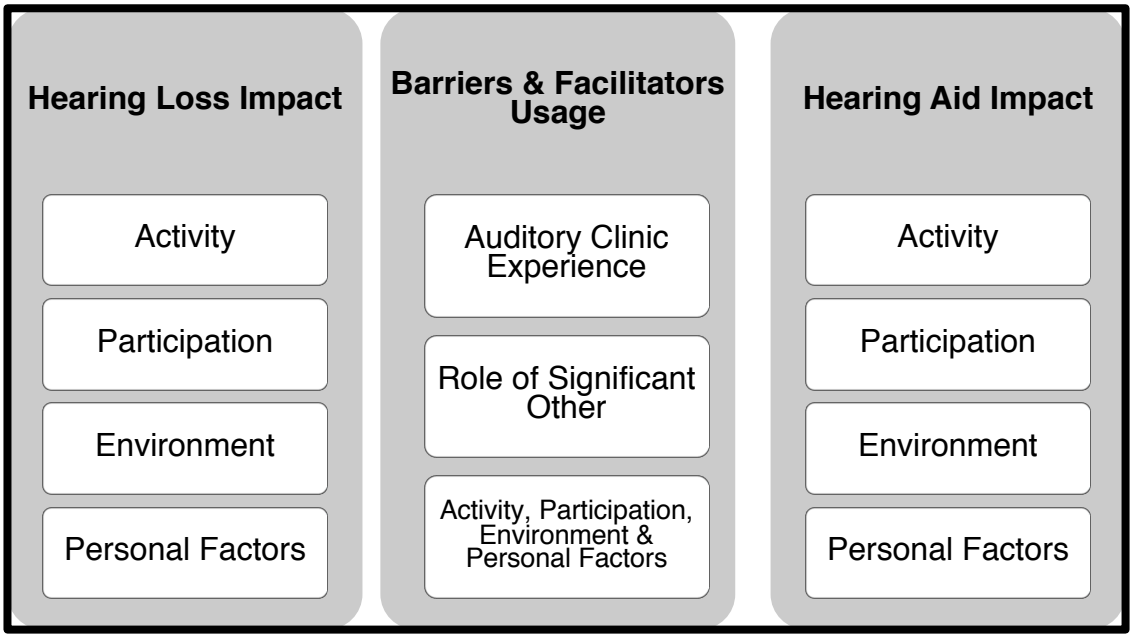
The structured interviews were audio-recorded and then electronically transcribed and then translated from Spanish into English. The transcripts were reviewed and formatted as a set of MS Word documents.

The interview data was securely stored and managed using the NVIVO software programme. The interview transcripts were uploaded as interview sources and filed under each coded (date of birth) participant. The sequential, four-stage data analysis process is described below.

2.20.1 Stage 1: Thematic Analysis

The qualitative data was analysed using Thematic Analysis, a systematic method for identifying and analysing patterns of meaning in a dataset.[182] The participant data was organised into pre-formatted themes using the NVIVO platform. A theme refers to a specific pattern of meaning found in the data, it may contain *manifest* content, directly observable across a series of interview transcripts, for example, explicit question responses or more *latent, implicit* content.[182] Initial codes were refined and expanded in an iterative process. Figure 17 identifies the inter-related, deductive themes which were used to categorise the data.

Figure 17: Themes



Three distinct themes were explored based on the impact of hearing loss, hearing aid impact and barriers and facilitating factors to hearing aid usage. The sub-themes were based on the key elements of the WHO International Classification of Functioning Framework, incorporating activities, participation, environment and personal factors. The case responses were categorised under each theme. For the purpose of identifying barriers and facilitating factors to intervention uptake, the clinic experience and the role of the significant other were also explored.

2.20.2 Stage 2: Data Interpretation

The theme-based data was reviewed and analysed. Emergent sub-themes, both expected & unanticipated as well as key relationships were identified, defined and visually mapped by the author before sharing the preliminary findings with an experienced qualitative researcher from the London School of Hygiene & Tropical Medicine. These discussions facilitated in-depth data analysis and interpretation. Theme specific quotations were selected and identity coded.

2.20.3 Stage 3: Comparative Interpretation

The qualitative interview data was compared and cross-referenced with the results from the quantitative survey data. This analytical process provided greater insight and understanding of the results. This analysis contributed to the development of collective, mixed method data summaries which are explored in the discussion.

2.20.4 Stage 4: Narrative Interpretation

Two participant stories were selected, described and presented as case studies. By analysing and interpreting the merged qualitative and quantitative data, a rich account and understanding of the participant was formed. This process focussed on the real-life interactions, experiences and feelings of hearing loss and the key barriers and facilitators to hearing aid uptake and usage.

2.21 Research Project Ethics

All qualitative and quantitative research activities were conducted in accordance and compliance with the procedures identified by the London School of Hygiene & Tropical Medicine Ethics Committee and the Local Ethics Board known as 'Zugueme Comite Etica Independiente', based in Guatemala City. With joint institutional approval (See Appendix 1 & 2) the following key practices were implemented:

- All case and control participants were invited to participate on a voluntary basis and were free to withdraw their participation at any time.
- Informed signed or thumb-printed consent was obtained from all cases and controls.
- All interviewed participants were provided with verbal and written information explaining the purpose and objectives of the project
- All participants were required to read (or listen to) an explanatory document and complete a signed consent form.
- All information provided by the respondent via the structured interview remained private and confidential.
- Data was stored on a password protected electronic tablet and automatically erased once the data was sent to the encrypted and password protected server.
- The author held all information on a password protected laptop and all document data was stored under an internal password.
- No personal information was shared with any third party
- All reported data was anonymised, removing the actual names and personal details of cases and replacing this with non-identifiable, fiction-based information.
- Participants requiring services were referred as appropriate. For instance, all potential controls identified with hearing loss were referred for hearing assessment and potential hearing aid fitting.

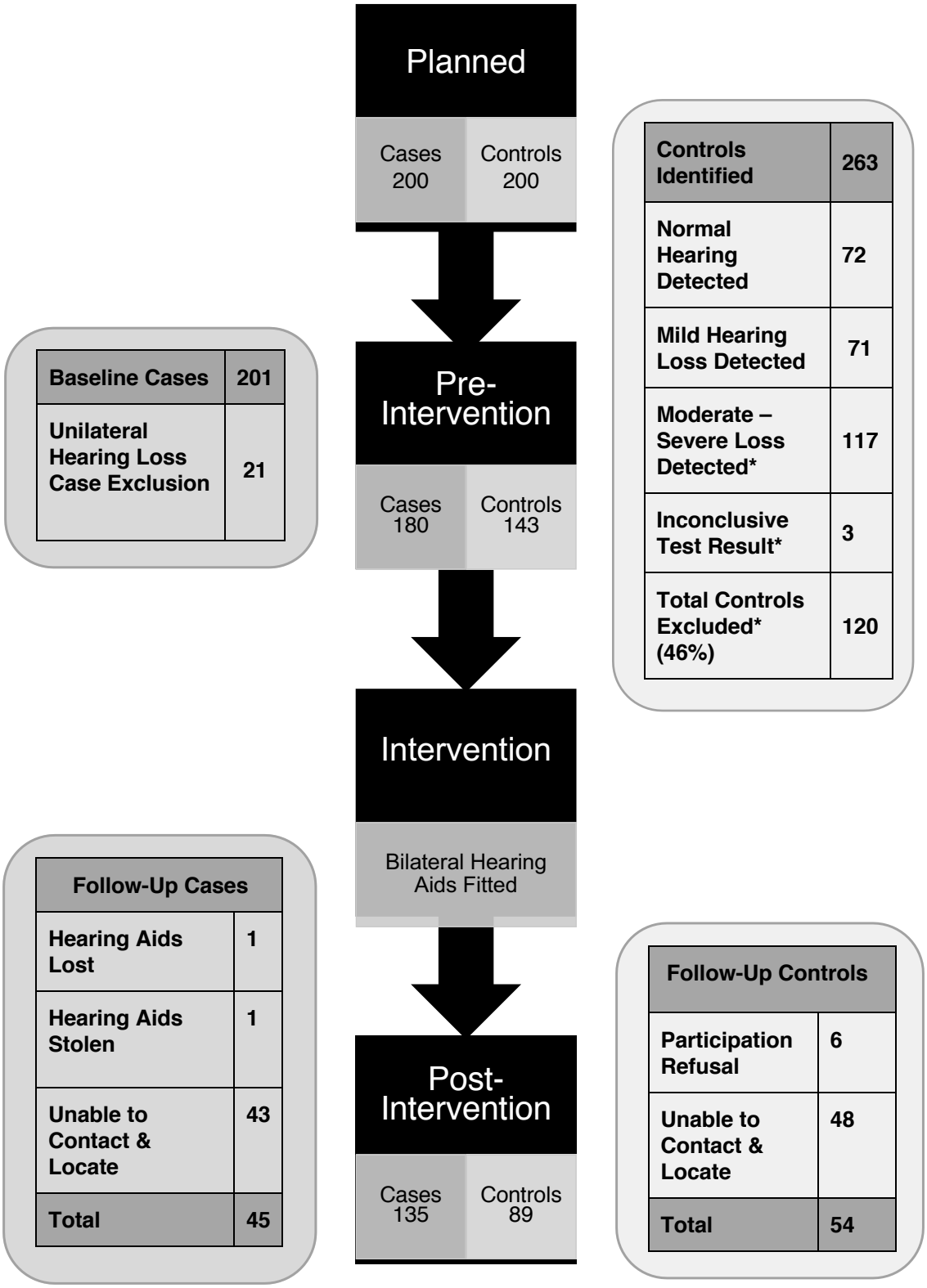
3. Quantitative Results

This research project planned to study a non-randomly sampled population of 400 subjects, including 200 cases and 200 controls. During the baseline, pre-intervention phase of this research study 464 potentially eligible subjects were identified including, 201 cases with moderate-profound hearing loss and 263 potential controls. (Figure 18)

Of the 201 cases identified, all agreed to take part in the study (100% response rate). However, 10% (21) exhibited unilateral hearing loss which is not classified as disabling hearing loss by WHO criteria and were therefore excluded from the analysis. All remaining case participants (180) had a bilateral, disabling hearing impairment of which 49% of cases had a moderate impairment, 39% were classified with moderate-severe and 12% had profound hearing loss.

At follow up 43 cases were unable to be located or contacted and 2 cases had either lost or had their hearing aids stolen. In total, 135 cases were followed up, representing a 67% response rate among the cases. For the control group, 263 potentially eligible adults were identified and screening tests for hearing loss were performed. The results of the screening tests demonstrated that 44% of all controls exhibited moderate-severe hearing loss, which is defined by WHO as disabling hearing loss, and therefore excluded from study participation. A further 1% of controls had inconclusive hearing test results and were excluded. Of the remaining 143 controls, 50% had normal hearing and the other 50% had mild, non-disabling hearing loss and were eligible for study inclusion. At follow up, six controls declined to participate in the study and 48 were unable to be contacted. The overall response rate among controls at follow-up was 62%. Figure 18 provides a sequential diagram of the case and control participant numbers throughout the research study.

Figure 18: Case & Control Participant Numbers



3.1 Characteristics of Cases and Controls at Pre-Intervention

Table 19 describes the key socio-demographic characteristics of the case and control participants. This study sample represented an older adult population with over 80% of all research participants over the age of 40 and both genders being equally represented.

Cases and controls were generally well matched on gender however, cases were significantly more likely to be in an older age category. Two-thirds of the cases (66%) were aged 60 years or above, compared with one-third (33%) of the controls. The majority of case and control subjects were married, and marital status was similar between cases and controls. There was no difference in case and control level of literacy and education. The socio-economic status of the participants was described by scores for household living conditions and asset ownership. The quartiles indicate the position of each case and control relative to the other subjects, ranging from a high number of assets or better living conditions to low or poorer. There was no significant difference detected in living conditions or household assets between cases and controls.

Table 19: Socio-Demographical Characteristics of Cases and Controls at Baseline

Baseline Characteristics		Cases	Controls	Age-Sex Adjusted OR (95% CI)	p-value
Age	<40	15 (11%)	14 (16%)	Baseline	<0.01
	40-49	10 (7%)	11 (12%)	0.85 (0.28, 2.61)	
	50-59	21 (16%)	31 (35%)	0.63 (0.25, 1.58)	
	60-69	43 (32%)	23 (26%)	1.74 (0.72, 4.24)	
	70+	46 (34%)	10 (11%)	4.29 (1.58, 11.66)	
Gender	Male	75 (56%)	39 (44%)	Baseline	0.09
	Female	60 (44%)	50 (56%)	0.62 (0.36, 1.07)	
Marital Status	Single	26 (19%)	20 (22%)	Baseline	0.16
	Married / Living Together	85 (63%)	55 (62%)	1.19 (0.61, 2.33)	
	Divorced / Separated	5 (4%)	8 (9%)	0.48 (0.14, 1.70)	
	Widowed	19 (14%)	6 (7%)	2.44 (0.82, 7.23)	
Literacy	Not at all	8 (6%)	3 (3%)	1.89 (0.49, 7.36)	0.37
	Little	13 (10%)	5 (6%)	1.85 (0.64, 5.39)	
	Well	114 (84%)	81 (91%)	Baseline	
Education Level	No Education	10 (7%)	4 (4%)	1.59 (0.47, 5.35)	0.57
	Primary	45 (33%)	34 (38%)	0.84 (0.48, 1.49)	
	Secondary/ University	80 (59%)	51 (57%)	Baseline	
Living conditions Score	Quartile 1 (poorest)	25 (19%)	22 (25%)	Baseline	0.32
	Quartile 2	35 (26%)	23 (26%)	1.34 (0.62, 2.91)	
	Quartile 3	48 (36%)	22 (25%)	1.92 (0.89, 4.12)	
	Quartile 4	27 (20%)	22 (25%)	1.08 (0.48, 2.41)	
Asset Score	Quartile 1 (poorest)	36 (27%)	20 (22%)	(Baseline)	0.14
	Quartile 2	41 (30%)	19 (21%)	1.18 (0.52, 2.68)	
	Quartile 3	31 (23%)	23 (26%)	0.64 (0.28, 1.47)	
	Quartile 4	27 (20%)	27 (30%)	0.50 (0.22, 1.12)	

3.2 Disability

Table 20 shows self-reported disability among cases and controls. Over 60% of all case participants perceived that they had a disability of which, 50% identified other forms of disability in addition to difficulties with hearing (e.g. difficulty with walking, vision, functional self-care, understanding or communicating). In contrast, only 26% of the control group were classified as having a disability. Cases were therefore significantly more likely to report experiencing a disability, whether this included or excluded hearing loss in its definition.

Table 20: Case & Control Self-Reported Disability

Baseline	Disability	Cases	Controls	Age-Sex Adjusted OR (95% CI)	p-value
Response	No	50 (37%)	66 (74%)	1 (Baseline)	<0.01
	Yes	85 (63%)	23 (26%)	4.88 (2.71, 8.79)	
Response Excluding Hearing Loss	No	68 (50%)	66 (74%)	1 (Baseline)	<0.01
	Yes	67 (50%)	23 (26%)	2.83 (1.58, 5.06)	

3.3 Employment & Income

Table 21 shows employment status among cases and controls. The majority (63%) of the control group were in paid work and contributed to the household income. By comparison, under half of all case participants (45%) were in employment although this difference did not reach statistical significance. Amongst those that were earning, individual earnings were significantly lower among the cases than the control group (overall 43% less). Overall, annual household income was lower (20% less) for case participant households than control households. The mean difference was 22% in household income and 54% in individual income between cases and controls.

Table 21: Comparison of Employment Status and Income of Cases & Controls

Employment	Response	Cases	Controls	Age-sex adjusted OR (95% CI)	p-value
Any type of work in last four weeks	No	74 (55%)	33 (37%)	0.59 (0.33, 1.08)	0.09
	Yes	61 (45%)	56 (63%)		
In the last four weeks, those without work who are looking or/and are ready for work	No	66 (89%)	29 (88%)	1.02 0.21, 4.87)	0.98
	Yes	8 (11%)	4 (12%)		
				Age-Sex Adjusted Mean Difference	
Income of Individuals US$ Per Month	Median (IQR)	156 (0, 407)	272 (88, 448)	- 165 (-293, -373)	0.01
Household Income US$ Per Month	Median (IQR)	493 (278, 832)	617 (326, 1153)	- 219 (- 409, -28)	0.02

3.4 Predictors of Annual Income

At baseline, predictors of annual income were evaluated among people with hearing loss. (Table 22) There was a trend towards a lower level of annual earnings in the oldest age group. Furthermore, men with hearing loss reported significantly higher (almost three times more) individual earnings than females. Hearing impairment severity was not significantly associated with income, but there was some suggestion that those with moderate hearing loss earned more than those with more severe levels of hearing loss.

Table 22: Predictors of Annual Income in Cases

Pre-Intervention Cases		Annual Individual Income (USD$) (Median, IQR)
Age Group	<40	1954 (0, 4071)
	40-49	3175 (1303, 7382)
	50-59	4641 (1873, 5903)
	60-69	2524 (176, 4234)
	70+	1347 (1, 4089)
	p-value	0.08
Gender	Male	3859 (529, 5781)
	Female	1357 (0, 2280)
	p-value	<0.001
Impairment Severity	Moderate	2442 (0, 4940
	Moderate-Severe	1466 (0, 4649)
	Severe-Profound	1608 (651, 3208)
	p-value	0.56

3.5 Expenditure

Table 23 explores household expenditure as a measure of household wealth, comparing people with and without hearing loss. Overall, total household expenditure and per capita expenditure were significantly higher in control households than case households, reflecting the greater wealth of control households. There were no significant differences in per capita expenditure when people were grouped by quartile among cases and controls.

There were also key differences between case and controls on specific categories of expenditure. Control participants spent more than double the amount on household items (such as furniture and home repairs) and 85% more on entertainment (Cable TV, hobbies & interests).

Controls also spent over three times more on education. By contrast, cases spent 38% more on healthcare. Expenditure on food was similar across the two groups.

Table 23: Comparison of Monthly Expenditure of Cases & Controls

Expenditure Products & Services		Cases	Controls	Age-Sex Adjusted Mean Difference (95% CI)	p-value
Mean Monthly Expenditure US$ (SD)	Total Household Expenditure	337 (300)	611 (828)	264 (108, 3123)	0.001
	Total Per Capita Expenditure	100 (89)	203 (383)	108 (38, 179)	0.003
					Age-Sex Adjusted OR (95% CI
Quartiles Per Capita Expenditure	Quartile 1 (Low)	35 (26%)	21 (24%)	1 (Baseline)	0.15
	Quartile 2	38 (28%)	18 (20%)	1.11 (0.49, 2.56)	
	Quartile 3	34 (25%)	22 (25%)	0.74 (0.33, 1.68)	
	Quartile 4 (High)	28 (21%)	28 (31%)	0.47 (0.21, 1.06)	
Categories of Per Capita Expenditure Mean US$ (SD)	Other	69 (90)	184 (466)	107 (22, 191)	0.01
	Food	144 (148)	173 (148)	27 (-14, 69)	0.19
	Household	58 (61)	155 (333)	99 (38, 160)	0.002
	Entertainment	10 (15)	18 (28)	8 (2, 14)	0.006
	Healthcare	38 (92)	26 (46)	-10 (-32, 12)	0.36
	Education	12 (56)	47 (129)	27 (2, 53)	0.04
	Tax, Legal Fees & Insurance	5 (16)	9 (26)	3 (-3, 9)	0.36

As shown in Table 24, there was no significant differences in expenditure among cases in relation to age, gender or hearing impairment severity at baseline.

Table 24: Stratified Case Expenditure at Baseline

Cases		Total Per Capita Expenditure (Mean, SD)
Age Group	<40	67 (74)
	40-49	127 (139)
	50-59	72 (65)
	60-69	103(82)
	70+	112 (93)
	p-value	0.19
Gender	Male	101 (89)
	Female	96 (89)
	p-value	0.76
Impairment Severity	Moderate	118 (101)
	Moderate-Severe	78 (66)
	Severe-Profound	93 (87)
	p-value	0.04

3.6 Activity & Participation

Table 25 explores the amount of time spent engaged in a range of activities of daily living by cases and controls. The allocation of time across all activities demonstrated that cases spent significantly more time on household tasks, for example, cooking, cleaning & caring for family members. Despite not reaching statistical significance the cases participated less in paid work and engaged in fewer leisure activities than controls. Female cases were more likely to engage in household tasks as compared to female controls. Among cases, men were twice as likely to engage in paid employment compared to women and over 40% more likely to undertake social visits and leisure activities. Female cases were twice as likely to engage in household tasks as compared with male cases.

Table 25: Comparison of Case & Control Activity-Time Usage at Baseline

Overall Mean % Time Spent:	Cases	Controls	Age & Sex Adjusted Mean Difference (95% CI)	p-value
Household Tasks	39%	33%	10.4% (2.3%, 18.5%)	0.01
Paid/Self Employment	9%	11%	-2.1% (-8.9%, 4.7%)	0.53
Household Work	6%	4%	1.0% (-3.2%, 5.3%)	0.63
Social Visits	12%	13%	-1.1% (-7.8%, 5.6%)	0.74
Leisure Activities	28%	32%	-8.0% (-16.8%, 0.8%)	0.07
Daytime Sleeping	4%	3%	0.7% (-2.6%, 4.0%)	0.69
Other	3%	4%	-0.9% (-4.3%, 2.5%)	0.61
Males				
Household Tasks	25%	18%	9.3% (-1.3%, 19.9%)	0.08
Paid/Self Employment	11%	11%	-1.0% (-12.1%, 10.2%)	0.86
Household Work	7%	5%	1.9% (-5.4%, 9.2%)	0.60
Social Visits	15%	14%	0.4% (-11.1%, 12.0%)	0.94
Leisure Activities	33%	39%	-7.9% (-22.0%, 6.3%)	0.27
Daytime Sleeping	4%	3%	-0.4% (-5.7%, 5.0%)	0.89
Other	5%	9%	-2.5% (-9.1%, 4.2%)	0.46
Females				
Household Tasks	55%	43%	12.7% (0.3%, 25.1%)	0.04
Paid/Self Employment	5%	10%	-3.1% (-11.4%, 5.2%)	0.46
Household Work	4%	3%	-0.1% (-5.0%, 4.8%)	0.97
Social Visits	8%	13%	-3.1% (-10.8%, 4.5%)	0.42
Leisure Activities	22%	27%	-9.1% (-20.2%, 2.0%)	0.11
Daytime Sleeping	4%	3%	1.6% (-2.5%, 5.8%)	0.44
Other	1%	1%	1.1% (-1.1%, 3.3%)	0.32

3.7 Depression

Table 26 displays the self-reported scores for the screening of depression using the Patient Health Questionnaire. The results show that few participants, whether cases (4%) or controls (1%), reached the threshold for a diagnosis of depression. Overall, cases were approximately twice as likely to experience depressive symptoms as controls. This is illustrated by a specific question: 'In the last two weeks how often have you felt down, depressed or hopeless, over a third (38%) of cases reported 'several days' or more compared to only 18% of controls.
Although these population numbers are very small and did not reach statistical significance, mental health symptoms of depression, expressed as a severity classification ranging from 'minimal – severe' were more common, and more severe among cases (28%) than control participants (12%).

Table 26: Comparison of Depression and Depressive Symptoms of Cases and Controls at Baseline

Depression		Cases	Controls	Age & Sex Adjusted OR (95% CI)	p-value
Depression	No	130	88	1 (Baseline)	0.50
	Yes	5	1	2.15 (0.23, 20.24)	
Depressive Symptoms Identified	No	97	78	1 (Baseline)	0.05
	Yes (>=minimal)	38	11	2.31 (1.01, 5.25)	
Severity of Depressive Symptoms	Not	97 (72%)	78 (88%)	1 (Baseline)	0.20
	Minimal	19 (14%)	7 (8%)	1.86 (0.67, 5.15)	
	Minor	13 (10%)	4 (4%)	2.40 (0.68, 8.43)	
	Moderate->Severe	6 (4%)	0 (0.0%)	N/A	

3.8 Quality of Life

Table 27 compares the overall and domain scores for subjective quality of life among cases and controls. The data demonstrates that cases had significantly poorer quality of life in all domains compared to controls, except for psychological quality of life and overall quality of life, where the difference did not reach statistical significance. The largest differences between cases and controls were demonstrated in the domains of physical, social relationships and environmental quality of life.

Table 27: Comparison of Quality of Life Between Cases and Controls at Baseline

Quality of Life	Cases Mean (SD)	Controls Mean (SD)	Mean Difference (95% CI) Adjusted for Age and Gender	p-value
Overall Quality of Life	3.6 (0.9)	3.8 (0.7)	-0.16 (-0.40, 0.08)	0.20
Overall Health	3.3 (1.0)	3.7 (0.8)	-0.38 (-0.65, -0.12)	0.004
Physical	14.6 (2.3)	15.8 (2.1)	-0.93 (-1.53, -0.32)	0.003
Psychological	14.6 (2.1)	15.1 (2.0)	-0.51 (-1.08, 0.06)	0.08
Social Relationships	15.3 (2.2)	15.9 (1.7)	-0.83 (-1.41, -0.25)	0.005
Environmental	12.8 (1.8)	13.4 (1.6)	-0.82 (-1.32, -0.32)	0.001

3.9 Self-Assessment of Hearing

The Hearing Handicap Inventory for Adults measures the self-reported emotional and social impact of hearing loss. The data in Table 28 shows that 79% of all cases reported that they had a ‘disability’ rated from mild-significant of which, almost half (49%) of all cases reported a ‘significant’ disability’. The historical term of 'handicap' has been substituted for the more appropriate and acceptable term of 'disability'.

Table 28: Hearing Handicap Inventory for Adults (HHIA) Scores Among Cases

Assessment of Hearing	Cases Mean (SD)
Overall Score (Out of 100)	46 (29.6)
Social Score (Out of 48)	20 (14.6)
Emotional Score (Out of 52)	26 (16.0)
Assessment Outcome	**Cases N (%)**
No Disability	28 (21%)
Mild-Moderate Disability	40 (30%)
Significant Disability	66 (49%)

Table 29 demonstrates that there are no significant differences in disability scores among cases, in relation to age, gender or severity of hearing loss.

Table 29: Stratified Hearing Handicap Inventory for Adults (HHIA)

Hearing Handicap Inventory for Adults		Mean Score (SD)	P-Value
Age Group	<40	39.7 (20.8)	0.40
	40-49	30.7 (24.0)	
	50-59	48.5 (27.6)	
	60-69	48.6 (31.5)	
	70+	48.0 (31.9)	
Gender	Male	48.5 (30.4)	0.29
	Female	43.0 (28.5)	
Impairment Severity	Moderate	49.5 (29.6)	0.39
	Moderate-Severe	43.6 (30.7)	
	Severe-Profound	40.1 (25.6)	

3.10 Impact of Hearing Loss: Cases vs Significant Other

The most frequently reported significant other was identified as the wife or husband. The mean self-assessment of communication score for cases was 68 (corresponding to a moderate level of disability) and the same questionnaire which was administered for significant others identified a mean score of 74. (Corresponding to a severe level of disability) As shown in Table 30 there is strong evidence that the significant others of cases rate hearing loss as having a higher impact (worse scores) than the case participants themselves (p=<0.01).

Table 30: Self-Assessment of Communication (SAC) Among Cases Versus Significant Other Assessment of Communication (SOAC)

SAC Case-Mean (SD)	SOAC Significant Other Mean (SD)	Difference	P-Value
68 (62.6, 72.5)	74 (69.5, 78.2)	6.3 (3.3, 9.3)	<0.01

3.11 Summary of Baseline Quantitative Results

Compared to controls without disabling hearing loss, individual earnings and household and per capita expenditure were significantly lower for cases. Cases spent less money on household items or leisure activities, but more on health care. No differences were detected in asset ownership. Despite the small population numbers, there was a positive association between cases and their experience of depressive symptoms. Cases were also identified as having a poorer quality of life across a range of domains, specifically relating to the health, physical, social and environmental aspects of quality of life, although not in overall quality of life. Cases spent more time performing household tasks but did not differ in other activities. The emotional and social impact of hearing loss was rated as a significant disability by almost half of the cases and was rated higher by their significant other.

Post-Intervention Results

3.12 Hearing Aid Usage

Hearing aid usage was measured and recorded in two ways. (1) Actual hearing aid usage data, which was electronically downloaded from the device during a follow-up clinic appointment and (2) Self-reported hearing aid use which was captured at interview. The majority (71%) of cases reported that they used their hearing aids on a daily basis. 93% reported that they used them for up to four hours per day and 69% reported wearing them for 8-16 hours per day. Actual hearing aid usage data showed that almost all (98%) cases wore their hearing aids for at least 1-4 hours per day and over half (53%) wore them for 8-16 hours per day. Figure 31 demonstrates that the majority (60%) of case participants accurately reported their hearing aid use. The prevalence of over reporting (23%) or under reporting (16%) was 39%, but this was usually by small amounts.

Figure 31: Self-Reported & Actual Levels of Hearing Aid (HA) Usage

		Self-Reported HA Usage			
	Usage	<1 Hour	1- 4 Hours	4-8 Hours	8-16 Hours
Actual HA Usage	<1 Hour	0	0	1	1
	1-4 Hours	5	6	6	6
	4-8 Hours	3	3	10	13
	8-16 Hours	0	0	7	53

Over Report Usage

Under Report Usage

At interview, 23 cases (17%) acknowledged that they do not wear their hearing aids every day and also reported the main reason for the lack of usage. (Figure 32) Whilst less than a quarter of these cases reported that their hearing aids do not help, 18% reported that their hearing aids were uncomfortable and over half (59%) indicated other reasons. 10 cases provided specific other reasons for non-daily usage which are identified in Table 33.

Figure 32: Reasons for Non-Daily Use (N=23)

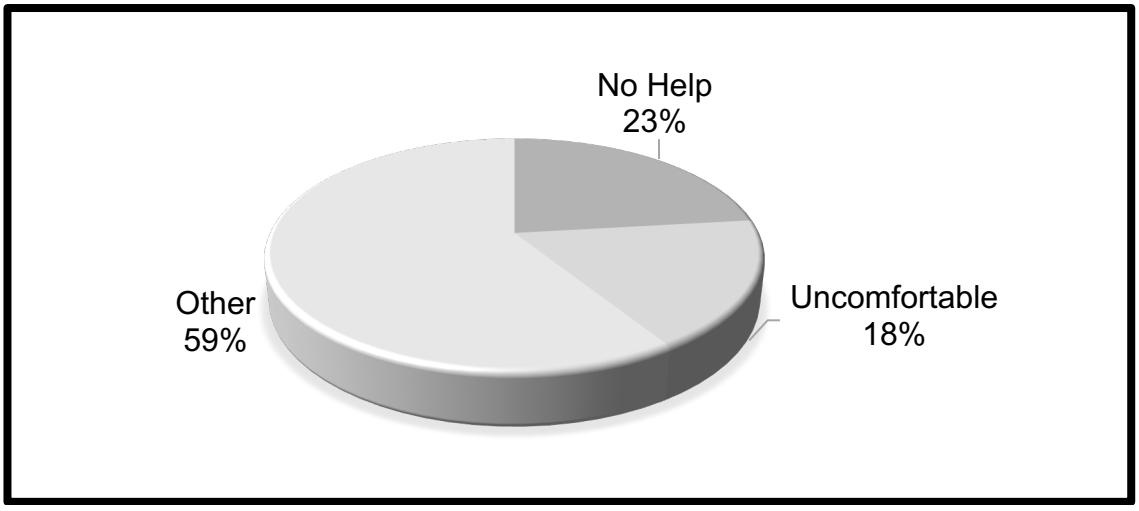


Table 33: Summary of Other Reasons (59%)

Non-Usage Domain	Response Frequency	Selected Quotes
Fitting & Function	4	'Do not understand how to wear them' 'The hearing aids no longer work and I have been unable to visit the clinic' 'I don't need to wear them all the time' 'I can't wear them at work'
Maintenance	2	'To save the batteries' (2)
Side Effects	4	'I suffer with tinnitus and wearing hearing aids sharpens the problem' 'They cause headaches' 'They make my ears itch' (2)

3.13 Employment & Income

Table 34 identifies no significant change in employment status for both case and control groups at follow up, compared to baseline and no change in the proportion of people looking for work. Individual income fell among the controls at follow-up compared to baseline, while household income increased among the cases between baseline and follow-up, but not among the controls. There was no change in household income among controls, or individual income among cases, between baseline and follow up.

Table 34: Comparison of Employment Status & Income at Baseline and Follow-up for Cases and Controls

Employment Status	Cases			Controls		
	Baseline (N=135)	Follow-Up	p-value	Baseline (N=89)	Follow-Up	p-value
Not Working	74 (55%)	74 (55%)	1.0	33 (37%)	37 (42%)	0.41
Working	61 (45%)	61 (45%)		56 (63%)	52 (58%)	
Not Looking for Work	66 (89%)	69 (93%)	0.56	29 (88%)	36 (97%)	0.32
Looking for Work	8 (11%)	5 (7%)		4 (12%)	1 (3%)	

Income $USD Per Month	Cases			Controls		
	Baseline (N=135)	Follow-Up*	p-value*	Baseline (N=89)	Follow-Up	p-value*
Income of Individuals	155 (0, 405)	121 (0, 405)	0.25	271 (88, 445)	162 (0, 472)	0.01
Household Income	490 (277, 828)	506 (234,1012)	0.03	614 (324, 1147)	540 (292, 1080	0.70

3.14 Expenditure

Table 35 demonstrates that at follow-up there was no significant change to case participant's expenditure at household or individual level. In contrast, at follow-up there was a decline in the level of household and individual expenditure for the control group compared to baseline.

Table 35: Comparison of Monthly Expenditure at Baseline and Follow-up for Cases and Controls

Monthly Expenditure ($USD)	Cases			Controls		
	Baseline (N=135)	Follow-Up	p-value	Baseline (N=89)	Follow-Up	p-value
Total Household Expenditure (SD)	335 (298)	379 (401)	0.23	608 (824)	421 (459)	0.02
Total Per Capita Expenditure (SD)	99 (89)	111 (147)	0.21	202 (381)	124 (167)	0.03

Table 36 demonstrates that there was no significant change in the categories of per capita expenditure at follow-up for either cases or controls compared to baseline. Healthcare costs fell among cases between baseline and follow up, but this change did not reach statistical significance.

Table 36: Comparison of per capita Expenditure Categories at Baseline and Follow-up for Cases and Controls

Categories of Per Capita Expenditure Mean US$ (SD)	Cases			Controls		
	Baseline (N=135)	Follow -Up	p-value	Baseline (N=89)	Follow-Up	p-value
Other	69 (90)	96 (252)	0.23	183 (463)	107 (176)	0.15
Food	143 (147)	137 (94)	0.67	172 (148)	166 (121)	0.77
Household	58 (60)	69 (81)	0.18	154 (331)	81 (142)	0.06
Entertainment	10 (15)	12 (18)	0.20	18 (28)	13 (20)	0.21
Healthcare	38 (91)	33 (63)	0.58	26 (45)	26 (57)	0.92
Education	12 (55)	20 (56)	0.23	47 (129)	20 (75)	0.09
Tax, Legal Fees & Insurance	5 (16)	11 (80)	0.39	9 (26)	7 (24)	0.62

3.15 Asset Ownership

Table 37 demonstrates that there has been no change in asset ownership among cases or controls at follow up, demonstrating a very similar pattern at baseline and follow up across all quartiles.

Table 37: Comparison of Asset Ownership at Baseline and Follow-up for Cases and Controls

Asset Quartile	Cases			Controls		
	Baseline (N=135)	Follow up	P-Value	Baseline (N=89)	Follow-up	P-Value
Q1 (Lowest)	36 (27%)	32 (24%)	0.14	20 (22%)	24 (27%)	0.14
Q2	41 (30%)	39 (29%)		19 (21%)	17 (19%)	
Q3	31 (23%)	38 (28%)		23 (26%)	22 (25%)	
Q4 (Highest)	27 (20%)	26 (19%)		27 (30%)	26 (29%)	

3.16 Activity & Participation

Table 38 identifies the core activities of daily living and the amount of time allocated to these activities as a percentage of the day for case and control participants at baseline and follow-up. On follow-up, cases demonstrated a statistically significant reduction in time spent in household tasks and an increase (not-statistically significant) in time spent in paid work. No other changes in time use were detected among cases or controls comparing follow-up to baseline.

Table 38: Comparison of Activities of Daily Living at Baseline and Follow-up for Cases and Controls

Overall Mean % Time Spent	Cases			Controls		
Activity	**Baseline**	**Follow-Up**	**p-value**	**Baseline**	**Follow-Up**	**p-value**
Household Tasks	39%	28%	<0.001	33%	33%	0.73
Paid/Self Employment	9%	16%	0.05	11%	14%	0.33
Household Work	6%	5%	0.81	4%	5%	0.49
Social Visits	12%	14%	0.41	13%	8%	0.18
Leisure Activities	28%	25%	0.85	32%	33%	0.92
Daytime Sleeping	4%	7%	0.12	3%	3%	0.61
Other	3%	5%	0.23	4%	2%	0.22

3.17 Depression

Despite the small numbers, at follow-up there was a significant reduction in depression and its related symptoms and severity in case participants as shown in Table 39. At baseline, 28% of cases reported depressive symptoms (minimal-severe), which reduced to 17% at follow-up. This represents a 41% reduction in the number of cases reporting symptoms of depression. Amongst the five cases with reported depression at baseline, all (100%) improved by follow-up, representing 40% with a reduced severity of symptoms at follow up and 60% of cases reporting no symptoms of depression.

Amongst cases who reported moderate to severe symptoms of depression at baseline, there was an 83% reduction in symptoms at follow-up. By contrast,

among controls there was no change in depression prevalence, and a small reduction in depressive symptoms.

Table 39: Comparison of Depression Scores and Symptoms of Depression at Baseline and Follow-up for Cases and Controls

	Cases			Controls		
Depression	**Baseline**	**Follow-Up**	**p-value**	**Baseline**	**Follow-Up**	**p-value**
No	130	135 (100%)	0.03	88	89 (100%)	0.32
Yes	5	0 (0%)		1	0 (0%)	
Depressive Symptoms Identified						
No	97	112	0.02	78	85	0.01
Yes	38	23		11	4	
Severity						
Not	97 (72%)	112 (83%)	<0.01	78 (88%)	85 (95%)	0.03
Minimal	19 (14%)	18 (13%)		7 (8%)	3 (3%)	
Minor	13 (10%)	4 (3.0%)		4 (4%)	0 (0.0%)	
Moderate->Severe	6 (4%)	1 (1%)		0 (0.0%)	1 (1%)	

3.18 Quality of Life

Table 40 demonstrates that at follow-up there was a significant improvement in quality of life of cases across all domains, except for social relationships which specifically relates to personal relationships, intimacy and support from friends. By contrast, at follow up there was no change in overall quality of life among the controls. However, an improvement in the psychological and environment domain and a reduction in the social domain was identified in controls at follow-up.

Table 40: Comparison of Quality of Life Scores at Baseline and Follow-up for Cases and Controls

	Cases				Controls			
	Baseline (SD)	Follow Up (SD)	Mean Difference (95% CI)	p-value	Baseline (SD)	Follow Up (SD)	Mean Difference (95% CI)	p-value
Overall Quality of Life	3.6 (0.9)	3.8 (0.9)	0.2 (0.0, 0.4)	0.01	3.8 (0.7)	3.9 (0.7)	0.0 (-0.1, 0.2)	0.56
Overall Health	3.3 (1.0)	3.7 (0.8)	0.3 0.2, 0.5)	<0.01	3.7 (0.8)	3.7 (0.8)	0.0 (-0.2, 0.2)	0.65
Physical Health	14.6 (2.3)	15.0 (2.5)	0.5 (0.1, 0.8)	0.01	15.8 (2.1)	16.2 (2.1)	0.4 (0.0, 0.9)	0.07
Psychological	14.6 (2.1)	15.5 (1.9)	0.9 (0.5, 1.2)	<0.01	15.1 (2.0)	16.0 (1.9)	1.0 (0.5, 1.5)	<0.01
Social Relationships	15.3 (2.2)	15.6 (1.8)	0.3 (-0.2, 0.7)	0.22	15.9 (1.7)	15.3 (1.8)	-0.6 (-0.2, -1.0)	0.01
Environment	12.8 (1.8)	13.7 (1.7)	0.8 (0.5, 1.2)	<0.01	13.4 (1.6)	13.8 (1.9)	0.4 (0.1, 0.8)	0.02

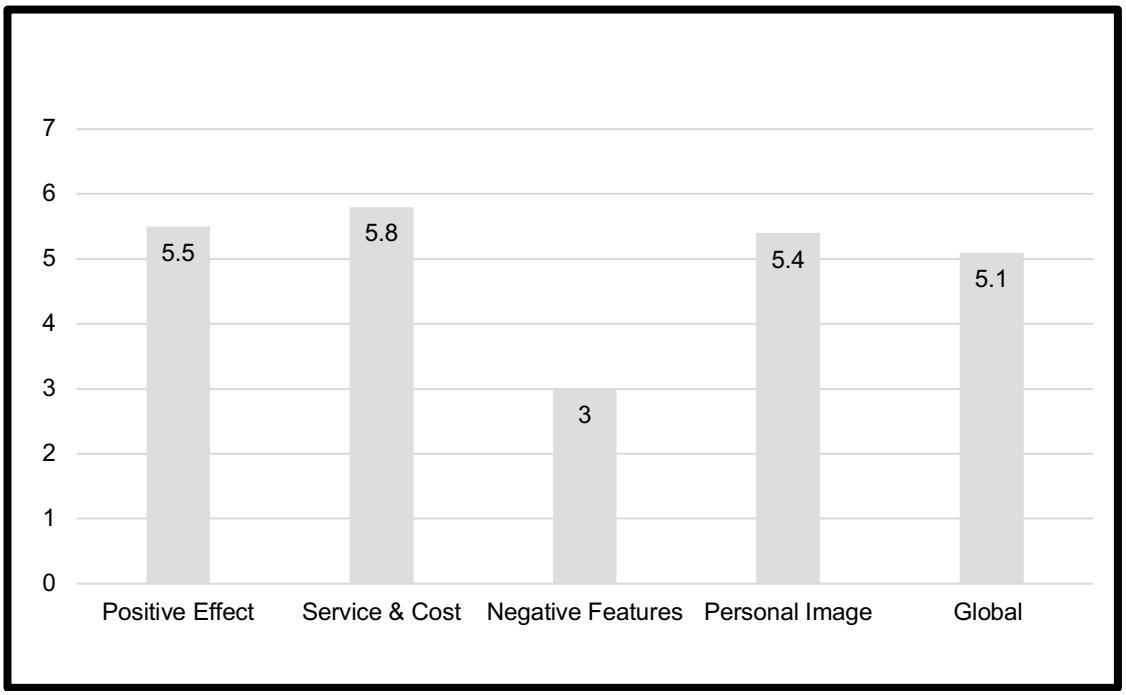
3.19 Impact of Hearing Aids

As shown in Table 41 and Figure 42, the total (global) mean score for satisfaction with amplification in daily life was 5.1. The constituent domains which relate to positive effect, service and cost and personal image equate to a *high* level of satisfaction with hearing aid use. Negative features of hearing aid use related to problems in background noise, feedback and telephone use had a mean score of 3, equating to a *low* level of satisfaction.

Table 41: Case Satisfaction with Amplification in Daily Life (SADL) Mean Global Score

Satisfaction with Amplification in Daily Life	Score
Global Mean Score	5.1
Global Score Range	4.5-6.2

Figure 42: Satisfaction with Amplification in Daily Life Mean Domain Scores



The ‘Hearing Handicap Inventory for Adults’ mean scores for cases at baseline and follow up demonstrated a significant negative difference, with 91% of all cases reporting a significant level of disability at follow-up as compared with 49% at baseline (Table 43). Similarly, the overall score, social score and emotional score all worsen between baseline and follow-up. The potential reasons for these unexpected results are explored in the discussion chapter.

Table 43: Case Comparison of Hearing Handicap Inventory for Adults Scores (HHIA) at Baseline and Follow-up

Assessment of Hearing	Pre-Intervention Cases Mean (SD)	Post-Intervention Cases Mean (SD)	p-value
Overall Score (Out of 100)	46 (29.6)	83 (24.4)	<0.0001
Social Score (Out of 48)	20 (14.6)	39 (11.8)	<0.0001
Emotional Score (Out of 52)	26 (16.0)	43 (13.2)	<0.0001
Assessment Outcome			
No Disability	28 (21%)	6 (5%)	0.02
Mild-Moderate Disability	40 (30%)	6 (5%)	
Significant Disability	66 (49%)	120 (91%)	

In contrast, the self-assessment of communication mean scores demonstrated a significant, positive response at follow up, as compared with baseline (Table 44). At baseline the cases reported a *severe level* of disability as compared with only a *slight level* of disability at follow-up. This numerical score represents less than half the level of difficulty with communication as compared with baseline.

Table 44: Case Comparison of Self-Assessment of Communication (SAC) at Baseline and Follow-up

Baseline Case-Mean (95% CI)	Follow-Up Case-Mean (SD)	P-Value
67.5 (62.6, 72.5)	27.1 (23.5-30.6)	<0.0001

Due to an incomplete and statistically insufficient data set at follow-up, the Significant Other Assessment of Communication (SOAC) question set has not been analysed.

3.20 Hearing Aid Experience

The case participants' perception of service delivery and hearing aid satisfaction levels were captured in the follow-up interview.

3.20.1 Audiology Clinic Experience

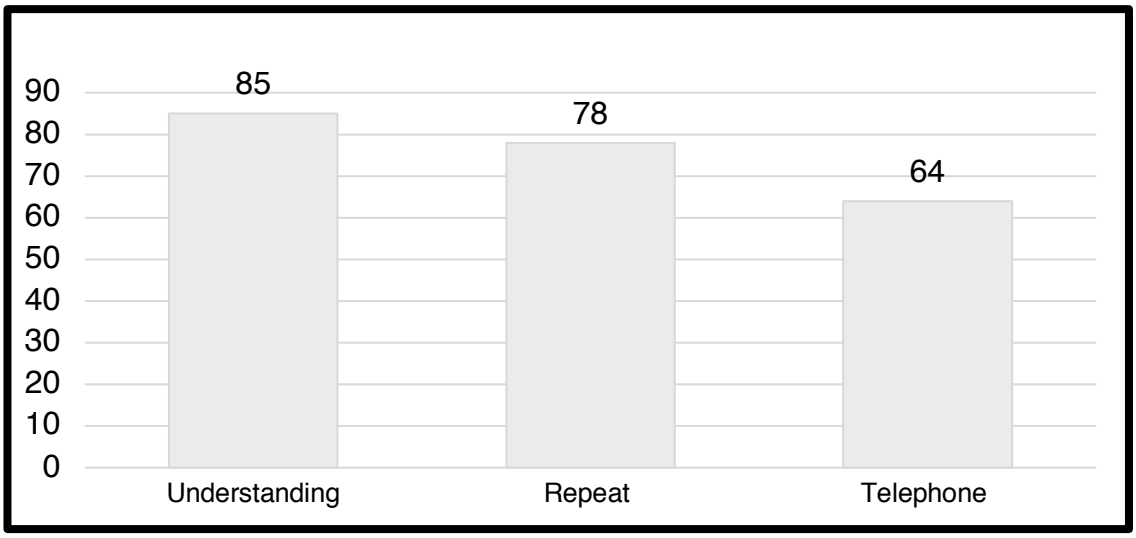
Almost all cases (96%) reported that the person who provided them with their hearing aids was highly competent and 93% of cases reported that the subsidized $50 USD contribution towards the cost of their hearing aids was considered a reasonable amount. Since hearing aid fitting, 88% of cases had attended a follow-up, review and maintenance appointment at the clinic.

3.20.2 Communication

At follow-up the vast majority of cases (85%) reported that in situations where they most wanted to hear better, over the last two weeks their hearing aids have significantly helped them in this specific situation. As shown in Figure 45, 85% of cases reported that wearing hearing aids helped them to understand the people they spoke with most frequently and 78% of cases reported that wearing hearing aids reduced the number of times they had to ask people to repeat elements of a

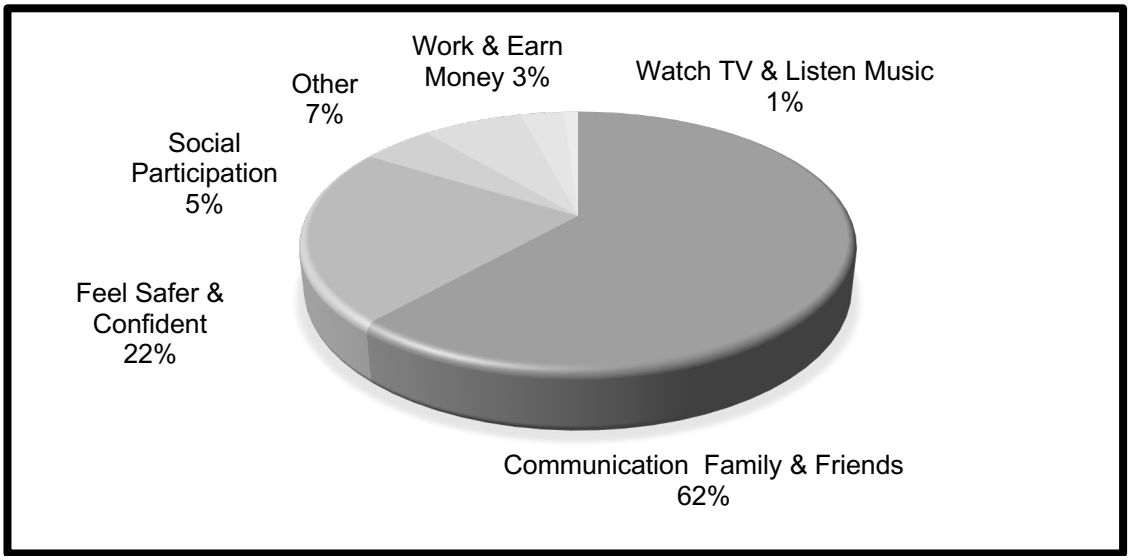
conversation. Almost two-thirds (64%) of cases reported that their hearing aids were helpful when using the telephone.

Figure 45: Communication Satisfaction Ratings (%) with Using Hearing Aids



As shown in Figure 46, case participants reported that the most important benefit of wearing hearing aids had been the ability to communicate with family and friends (62%) and almost a quarter reported that most importantly they felt safer and more confident. (22%)

Figure 46: Most Significant Hearing Aid Benefit Among Cases (%)



3.20.3 Health & Wellbeing

As shown in Figure 47, almost all cases (94%) reported that hearing aids had significantly improved their enjoyment of life and 90% of cases reported that wearing their hearing aids had improved their self-confidence. Three quarters of all cases (75%) reported that they felt that wearing hearing aids did not make them seem less capable and almost all cases (93%) were convinced that obtaining hearing aids was in their best interest.

Figure 47: Health and Wellbeing Satisfaction Rating at Follow up Among Cases (%)

3.20.4 Hearing Aid Maintenance

As shown in Figure 48 & 49, the vast majority of cases (91%) were satisfied with the dependability of their hearing aids, in how infrequently they needed repair and (86%) the frequency of cleaning required. Cases were satisfied with the life of the hearing aid battery (73%) and ease at which it could be changed. (90%) Over half of all cases (58%) were satisfied with the ability to adjust their device volume. The vast majority of all cases (90%) were satisfied with their access to hearing aid battery supplies, as well as hearing aid repair and maintenance services. (81%)

Figure 48: Hearing Aid Maintenance Satisfaction Score Among Cases (%)

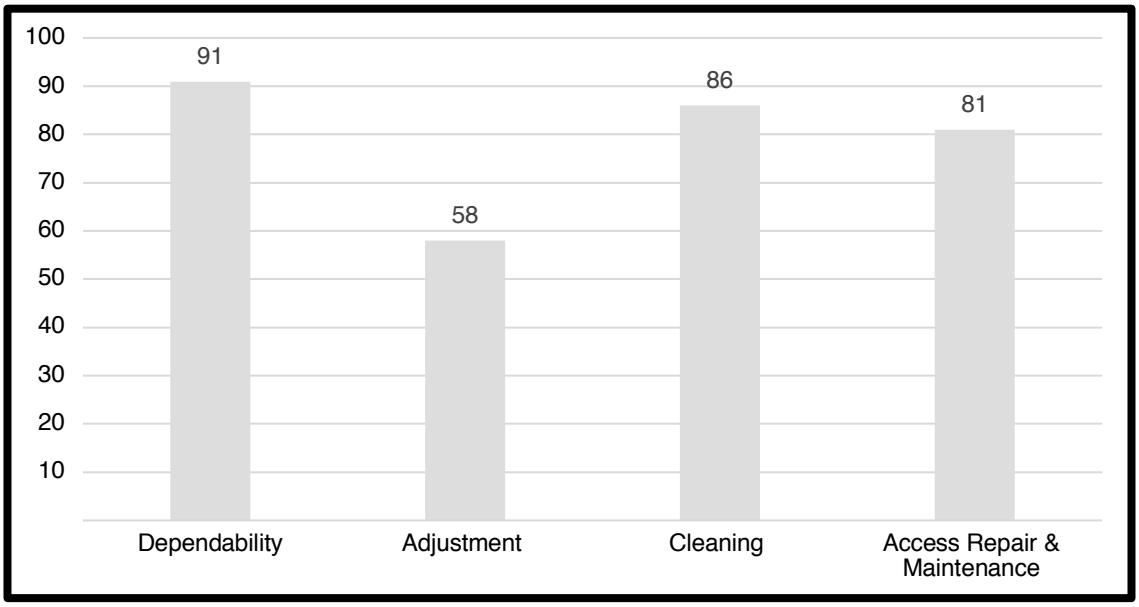
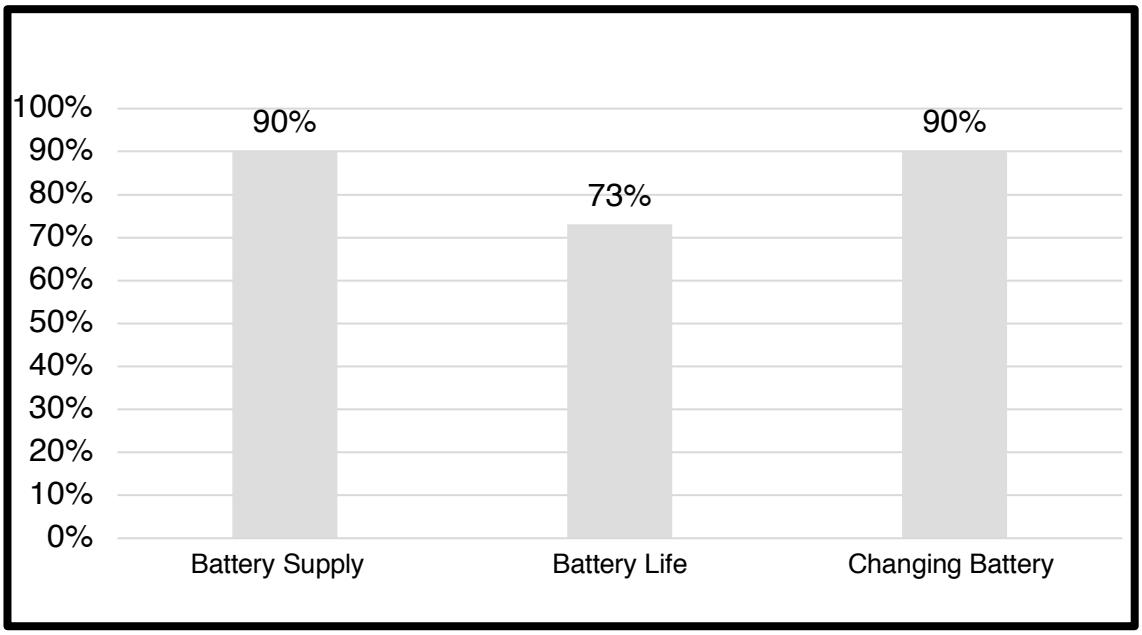


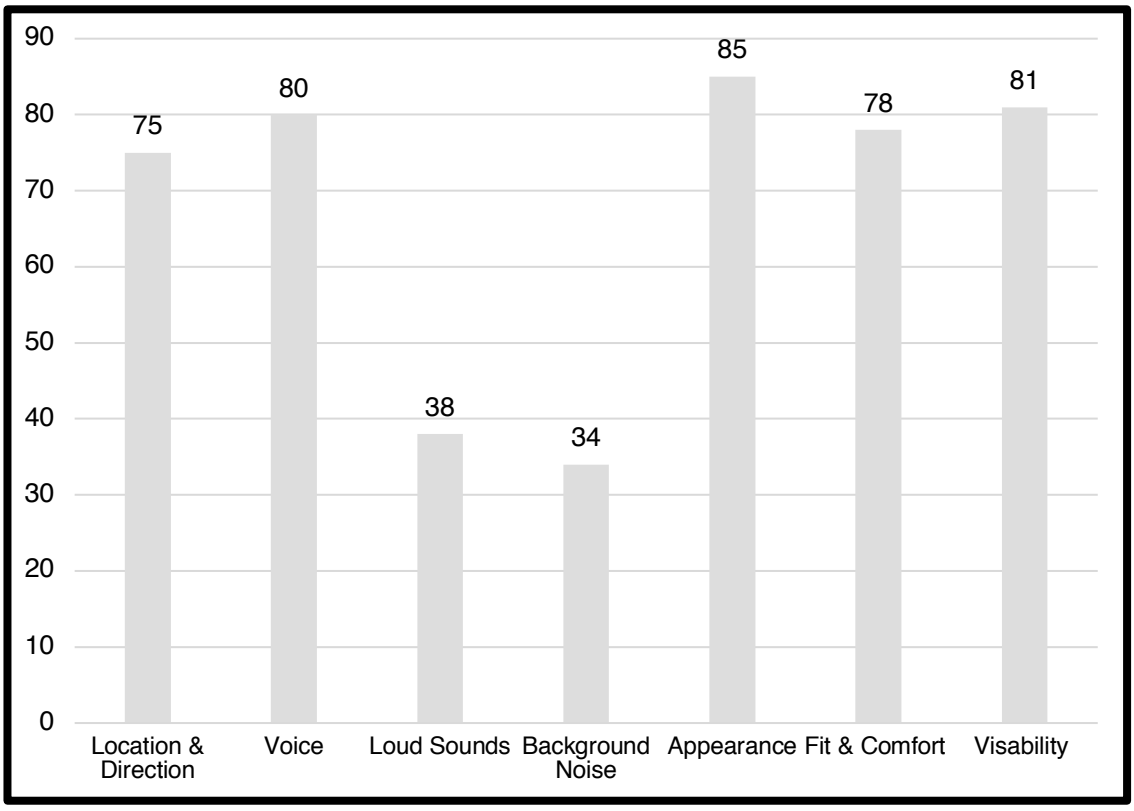
Figure 49: Hearing Aid Battery Satisfaction Rating Among Cases (%)



3.20.5 Hearing Aid Functionality

Hearing aid functionality considers how effective the devices are in providing amplification. As shown in Figure 50, three quarters (75%) of cases were satisfied with the ability to tell the location and direction of sounds and 80% of cases were satisfied with the sound of their own voice when wearing their hearing aids. Only 38% of cases were satisfied with the comfort of loud sounds when wearing their hearing aids and over one third (34%) of cases reported frustration when they're hearing aids picked up background sounds that kept them from hearing what they wanted to hear. The vast majority of cases (85%) reported that they were content with the appearance of their hearing aids and were satisfied with the visibility to others (81%) and the overall fit and comfort of their devices. (78%)

Figure 50: Hearing Aid Functionality Satisfaction Rating Among Cases (%)



3.21 Summary of Follow-up Findings

At follow-up, hearing aid usage was generally high with the majority (71%) of cases using their hearing aids on a daily basis. Of those measured, 98% of cases reported and actually wore their hearing aids for at least 1-4 hours per day. At follow-up there was a significant improvement in quality of life of cases across all domains, except for social relationships and 88% of case participants reported that hearing aids had positively changed their enjoyment of life. This improvement was not matched to the same extent among the controls, between baseline and follow-up.

There was no significant change in employment status for either case or control groups at follow up or in the proportion of people looking for work. Individual income fell among the controls at follow-up compare to baseline, while household income increased among the cases between baseline and follow-up, but not among the controls. There was no significant change to case participant's per capita expenditure at household or individual level. In contrast, for the control group at follow-up there was a significant decline in the level of both household and individual per capita expenditure. At follow up the allocation of per capita expenditure for cases and controls was similar and there has been no change in asset ownership among cases or controls at follow up.

Although based on a small population size, there was a 41% reduction in the number of cases reporting symptoms of depression. At baseline, 27% of cases reported depressive symptoms (minimal-severe), which reduced to 16% at follow-up. By contrast, among controls there was no change in depression prevalence, and a small reduction in depressive symptoms. Apart from one unexpected, reported outcome, the results of this research project generally show that hearing aids have a positive impact. Cases reported that the most significant benefit of wearing such devices had been the ability to communicate with family and friends (56%) and the vast majority (90%) reported that hearing aids had improved their self-confidence. The majority of cases were satisfied with the functionality and maintenance requirements of their hearing aids.

4. Qualitative Results

This section of the results chapter provides a qualitative analysis of the in-depth interviews conducted with cases after they had been fitted with their hearing aids. The impact of hearing loss and the use of hearing aids is analysed through the lens of the case participant, aiming to capture and record their personal experiences, thoughts and feelings. The International Classification of Functioning and Disability framework and its constituent elements are used as a roadmap to guide the comprehensive analysis of the data. The core elements of activity, participation, environmental and personal factors are used to structure the analysis, integrating illustrative participant quotations with interpretative text. This analysis is followed by two case studies which explore the dynamic, situational context of the participant's experience. The primary researcher and author of this research project has a bilateral hearing impairment and wears hearing aids in both ears, and his reflection on how this influenced the planning, implementation and analysis of the fieldwork is explored in the final section of this chapter.

4.1 Participant Demographics

Twenty-two in-depth interviews were undertaken with cases during the post-intervention phase of this research project. The participants had a mean age of 63 and an age range of 27-80 years. All cases had been assessed with a bilateral moderate to severe hearing impairment and had been fitted with hearing aids within the last 6-9 months. An equal number of male and female adult cases were included, and all participants lived within a 150 km radius of Guatemala City. At the discretion of the participant, a quarter of all interviews were undertaken in the presence of a significant other person, such as a wife, husband or family member. As described in the Methods Chapter, questions were designed and administered for a case specific in-depth interview, however if a family member was present and actively participated in the interview their response was also recorded.

4.2 Impact of Hearing Loss

This section explores the multi-dimensional impact of hearing loss. The key elements of the International Classification of Functioning and Disability framework, including activity, participation, personal factors and the environment are used to structure the analysis and provide interpretation.

4.2.1 Activity

Activities are tasks or actions which vary in nature, complexity and duration. The activity may have physical or cognitive elements and is performed by the case in a variety of settings. For example, activities of daily living such as dressing, preparing a meal or washing clothes. During the in-depth interview, participants described their routine, day-to-day experiences of hearing loss. Activities that primarily involved a form of communication were specifically challenging, such as using the telephone. In these situations, the visual cues or verbal clarity may be compromised and using the telephone was often restricted or avoided.

> ‘I have a son who lives in the USA, when he calls me on the telephone I was like, what? What did you say? Ahhh? I can´t hear you, I don´t understand what you are saying!’ (M23)

Participants explained that simple activities were often the most challenging and required the assistance of others. For instance, a 24-year old female provided a practical example of how her hearing impairment impacts on her home life and the dependency on her children:

> ‘It affects me very much, as not hearing, when there is a knock at the door, I don´t hear and my kids tell me someone is knocking and then I have to go running to see who it is.’ (F22)

Many of the cases acknowledged that they had been unaware of their hearing loss and thought that they were able to hear ‘normally’. Frequently, it was a series

of interactive experiences with family members that alerted them to their sensory challenge. For instance,

> 'Because my mom spoke to me and I did not pay attention to her, and that is how I found out.' (F22)

Some cases thought that external factors, such as the way other people spoke were the reason why they were unable to hear, for example;

> 'I didn´t know I had a problem, I never went to the doctor for that, it was just the problem that I was ah …? Ah ….? I thought it was normal and that the person was speaking low.' (M5)

To be able to hear, cases acknowledged that they required other people to employ compensatory behaviours;

> 'I realized that people spoke to me and I couldn´t hear unless they shout out loud.' (M18)

Family members identified a hearing impairment by the specific behaviours and actions of the case:

> 'We realized she had a problem because she had the radio and television on very loud all the time.' (M11)

4.2.2 Participation

Participation is defined as the involvement in a life situation or event, for example, engaging in work or taking part in social occasions.[69] Participation usually requires some form of social interaction to which communication may play an important role. In-depth interviews were undertaken with cases who were either in full or part-time employment (45%) and those who were retired (55%).

The form of employment and their role varied from trained, professional work such as a church pastor, nurse and health promotion officer to skilled labourer or manual worker, such as a car mechanic, butcher or agricultural farm worker. Many of these roles and responsibilities required participants to socially interact and effectively communicate with a range of co-workers, customers or members of the community. For example, an educational supervisor reflected on his experience in meetings and the challenges of communication with work colleagues:

> ‘I visit many teachers and we also have lots of meetings with institutions. My work involves many meetings and when they speak to me, I only laugh or smile … but the truth is that I didn´t understand what the conversation was about.’ (M05)

Similarly, a Delivery Driver described the impact on communication, the effects of background noise and the compensatory actions required to communicate with co-workers:

> ‘My job is to deliver beauty supplies to the department stores. When I am driving I have an assistant to help me to find the addresses, and he helps me with the instructions to get there. As I can’t hear, I have to lip read, I have to stop the car, close the windows and pay attention to him.’ (M16)

In this example, the hearing impairment affects the performance of the driver, requiring him to stop and receive the travel directions. Such repetitive, compensatory actions impacts on delivery times and work efficiency. Participants also reflected on their experience of hearing loss within the home environment and the impact on their ability to socially interact and participate with family members. A 66-year-old participant described the impact of hearing loss on his ability to communicate with family members and the effect this had on their relationship:

> ‘I had problems communicating, for example if I was together with my family and they were speaking, I couldn´t understand, so I couldn’t share with them and left to my room. I tried to get away from them, my wife did notice. I guess that at first they thought that I don´t love them or didn´t care.’ (M14)

Most participants described how their hearing impairment affected their ability to communicate and understand what someone else was saying. Participants reported that other people’s voices sounded too low, muffled or unclear and that they frequently missed all or part of a conversation. Participants explained that their lack of response or understanding in a conversation was often perceived by others as an annoyance or interpreted as the participant being unwilling to engage in a conversation. A consequence of this negative response meant that some participants deliberately withdrew or avoided engaging and socially interacting with other people. This was demonstrated by a 71-year old male who explained that he avoided going out because of the negative response he received from other people within his community:

> ‘I tried to avoid going out because when I did people tell me that they talk to me or say ‘hello’ and I never answered back. And they were kind of angry, I had to explain that it was because I couldn´t hear them.’ (M17)

This negative perception extended from social situations to the workplace setting, as described by a 55-year old male:

> ‘My family and work … it was difficult to hear what they were telling me and that annoyed the person that was talking to me’ (M15)

These experiences demonstrate the challenges of communication for participants with hearing loss. Participants also identified some of the ways in which they attempted to compensate for their hearing loss, for example, either by physically

repositioning themselves or by recruiting an assistant to help interpret or communicate on their behalf. In some instances, cases would attempt to conceal their hearing loss, pretending that they had heard and respond with laughter or a facial gesture. This was demonstrated by a pastor who described the communication challenges he encounters within his church community:

> ‘There are persons that are very sick, so the family calls us to go and pray for them, and they are so sick that they have difficulties in speaking, so I need to be closer to them and I have to bring someone to help me understand what they said.’ (M10)

Participants reported that when using verbal or non-verbal compensatory actions or gestures to mask their hearing loss, they sometimes inadvertently provided an incorrect or inappropriate response. For example, smiling at something that should elicit a sad response or responding to a miss-heard question with the incorrect answer. Participants explained that such incidents affected their performance at work. Such a response had a detrimental effect on how they were perceived by customers or co-workers, often questioning their level of competence, understanding and ability to perform their role. For example, a female nurse reported:

> ‘At my work … they teased me and told me, are you deaf or what? They also said, ‘oh you don´t hear me or you don´t understand me’ (F12)

These responses may be culturally or socially normalised and expressed without knowing the impact and feelings of exclusion that they may evoke.

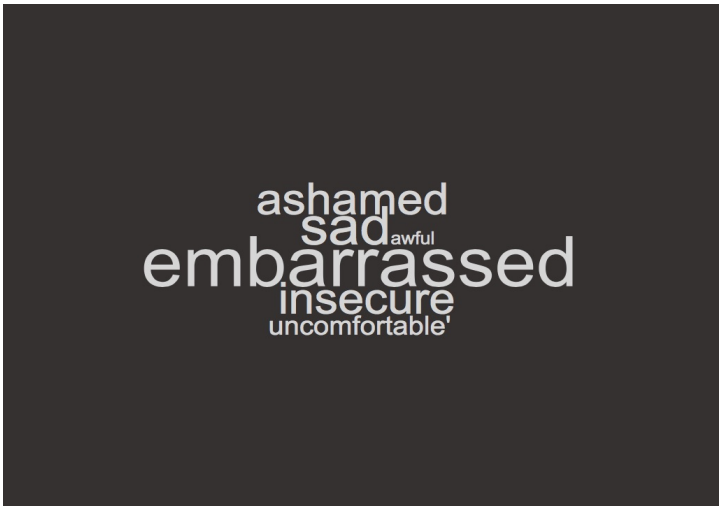
4.2.3 Personal Factors

Personal factors comprise of the physical, social and psychological context in which people live and conduct their lives. The impact of hearing loss was explored from this intrinsic context. Participant experiences of hearing loss and its associated challenges, frequently generated a physical response such as, a self-

imposed withdrawal from a social situation or limited participation or avoidance of activities involving communication such as using the telephone, as described earlier. Such actions were accompanied by a psychological or emotional response.

Most participants expressed their concern about how other people perceived and responded to their communication challenges. Any negative verbal or behavioural response affected how they felt. Participants used a broad range of verbal descriptives to explain how this made them feel and these are captured in Figure 51. This word cloud demonstrates the proportionate responses based on the frequency of the descriptive word use.

Figure 51: Case Descriptions of the Emotional Impact of Hearing Loss



Participants reported that other people's preconceived opinions and lack of understanding manifested as inaccurate judgements and assumptions being made about their level of intellect, capability or comprehension. For example a 65-year old male describes his experience of hearing loss and how the response of others made him feel:

> 'I felt embarrassed of being in society, because I couldn't hear anything I had to ask again, but sometimes they gave me the answer and sometimes they didn´t. I felt very uncomfortable and

> felt very ashamed because they explained what I have to do and I always missed something.' (M03)

Similarly, a 76-year old female describes the negative, emotional response of others to her inability to hear a conversation. Such a response causes distress and confusion.

> 'They get angry, because I can´t hear what they have to say. I feel sad, because they get angry at me and I don´t understand why.' (M18)

These responses have implications for long-term mental health and wellbeing. These participant experiences and verbal descriptives suggest that participants sometimes felt stigmatized, facing prejudice, discrimination and social exclusion by others.

4.2.4 Environmental Factors

Environmental factors, such as background noise, lighting levels and the physical distance between the auditory source and the participant are extrinsic factors that may impact on activity performance and social participation among people with hearing loss. For example, a 71-year old male participant explained that whilst walking on the streets of his neighbourhood:

> 'I can´t hear the cars. I hear they come from one side, but they come from the other.' (M18)

Most participants reported being unable to hear the engine noise of a car or detect the proximity or direction of the traffic on the roads. For pedestrians with a hearing impairment this has personal safety implications with the risk of a road traffic accident.

4.3 Impact of Hearing Aids

Participants had been assessed and fitted with bilateral hearing aids within the previous 6-9 months and most reported that they used their hearing aids on a daily basis for a varied amount of time. (The quantitative results section provides a detailed account of hearing aid usage)

4.3.1 Activities & Participation

Participants were asked to share their experience of using hearing aids and to identify a practical example of when their devices had provided the most help. For example, a 76-year old female described the positive impact that wearing hearing aids had made to her ability to communicate and socially engage with others.

> 'Before, I had to make a big effort to understand, but now I can hear. I used to hear only part of the conversation and not take part. That is what I value the most, I enjoy speaking with family and friends.' (F09)

This example demonstrates a significant, positive impact, with the participant's experience of conversation transforming from one of 'effort' and 'avoidance' to an activity that is 'valued' and 'enjoyed'. Participants recognised that prior to using their hearing aids, greater effort and concentration was required to listen and understand a conversation. They reported that the use of hearing aids had significantly improved their performance in a range of daily activities. For example, a 63-year-old female participant identified several, specific activities that had become much easier and more comfortable to manage:

> 'When someone talks to me, when they knock at the door and I take the volume of the T.V. lower and can still hear!' (F01)

Participants shared their experience of wearing their hearing aids at work. One 68-year old hospital nurse described the communication challenges of hearing

loss and the positive impact that wearing her hearing aids had made including the ability to communicate and perform her duties more effectively.

> ‘At my work hearing aids have helped me very much because I understand the persons that are speaking to me, before I didn´t know what to do because I couldn´t understand what they wanted. … It was tough because I had to guess what they were saying - I could hear them but, could not understand.’ (F12)

Similarly, the male church pastor who previously described how a hearing impairment affected his ability to conduct his work in the community, reported that hearing aids had significantly improved his ability to communicate within challenging, and sensitive environments. He was now able to work independently, without the need for an assistant to provide communication support. Such positive changes in working practice have implications for enhancing working relationships and improving productivity. A housekeeper also reported on the benefit of being able to perform her role more easily and effectively:

> ‘I wear my hearing aids all the time, if I am in the laundry sometimes the phone rings or the bell rings … before, I couldn’t hear that’ (F04)

Under such circumstances, the use of hearing aids reduced the amount of effort required to complete a task. This enabled the participant to effectively perform their role and responsibilities and in the long term, may contribute to greater job satisfaction and security. A 55-year old male health promotion officer acknowledged the contribution that his hearing aids had made to his road traffic awareness and safety whilst at work and traveling to and from work meetings:

> ‘I work in the streets … I need to hear everything around me in-order to take care of myself. I need to be aware of cars and anything else when I walk’ (M15)

Car ownership and access to a vehicle was uncommon amongst the participants and most reported using public transport, such as a bus to travel to work, visit friends and family or attend their clinic appointments. However, one 39-year-old male who used a car as part of his work, described the impact of hearing aids on his ability to drive more safely and confidently:

> ‘I hear everything, even the engines from cars, even if I am not seeing them in the mirrors. Or if someone is coming on my left to pass me. Now I hear better than my kids and wife!’ (M05)

Enhanced safety and security awareness was also experienced by a 27-year old female while she was walking in the street:

> ‘When I don´t have them [my hearing aids] I do feel a little bit insecure, but when I wear them, I feel safe’ (F08)

Participants reported specific factors that contributed to their perception of safety, and security including an enhanced sensory awareness of the environment and the ability to hear oncoming road traffic or people.

4.3.2 Personal Factors

The in-depth interviews captured how participants felt about wearing hearing aids and the impact that this intervention has had on their psychological wellbeing and mental health. For example, one 63-year-old female simply summarised her feelings by stating that with the fitting and use of her hearing aids;

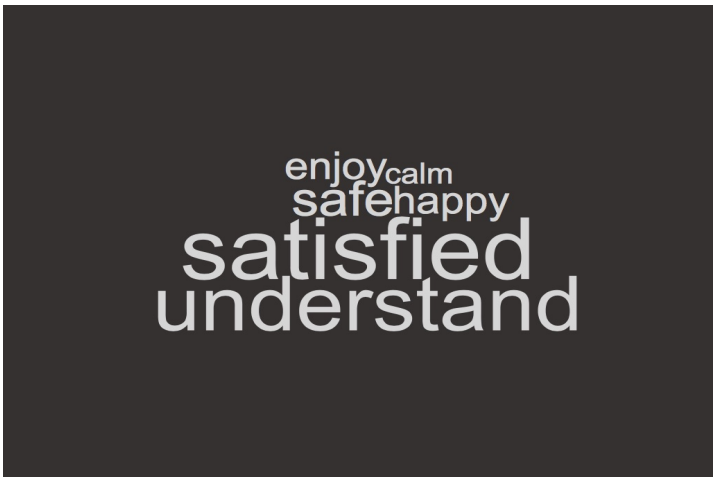
> ‘I hear better, I feel better.’ (F01)

A 65-year old male agricultural farmer reported on the psychological impact of hearing loss and the positive experience of wearing hearing aids, which contributed to his improved enjoyment of active, social participation.

> ‘Before, at work, it felt very uncomfortable and I felt very ashamed because they explained what I had to do and I always missed something. Now, it is a pleasure and I feel very happy speaking with others.’ (M03)

All participants were asked to express how they felt about using hearing aids. Based on frequency, the most common emotional responses were recorded and presented in Figure 52. Descriptive terms such as ‘uncomfortable’ and ‘ashamed’ were replaced with phrases that expressed pleasure and happiness like ‘satisfied’ and ‘safe’. This provides a powerful example of how such an intervention affected the emotional and mental state of the participants.

Figure 52: Case Descriptions of the Emotional Impact of Hearing Aid Use



Several participants reported that they struggled to independently fit their own hearing aids or replace the batteries. For example, the daughter of a 73-year old male identified the practical challenges of wearing hearing aids and consequently, the restricted time-frame in which they could be worn.

> **‘**He (my father) lives alone, so he can´t put them on [hearing aids] by himself, just when I come to visit him, I put them on him’ (M02)

Similarly, a 62-year-old female reported on the reliance of her daughter to help maintain the use and function of her hearing aids:

> ‘My daughters do it, they change the batteries for me and they help me to put them on’ (F13)

The reason for not being able to self-fit the hearing aids was due to a range of bodily impairments such as hand, arm and shoulder weakness or a lack of digital dexterity and coordination in performing such a detailed operation. These physical limitations were caused by co-morbidities such as degenerative disorders, such as arthritis, musculoskeletal injury or neurological impairment. Some participants provided multiple reasons or justification for limiting the use of their hearing aids beyond their physical capability to fit and put the hearing aids. A key limiting factor was the desire to conserve battery power by only using the devices at pre-planned social events, driven by the financial cost and affordability of replacement batteries. This was demonstrated by a 73-year old male who acknowledged a range of contributory factors as to why he does not always wear his hearing aids:

> ‘For me it is difficult to put them on and secondly that I work on the field, so I don´t wear them, I just wear them when I’m at home, or when my children come, as I don´t go out often… I don’t use them because I am saving my batteries.’ (M02)

Several respondents expressed their concern regarding the cost and life-span of their hearing aids and their ability to afford and access replacement devices in the future. A 65-year-old male expresses his concern for the future:

> ‘I was told in the clinic, that these hearing aids will only last 5 years, and what happens in five years if they don´t work anymore? Will my ears get worse for not wearing them?’ (M03)

The answers to such questions were provided by the clinic staff and participants were reassured of the ongoing support and maintenance provision of their devices. However, due to the high cost of the devices and their charitable donation requirement, no assurances could be provided about long-term provision or replacement.

4.3.3 Environment

A 65-year-old male identified how frequently he uses his hearing aids and describes how he does not use them under certain environmental conditions in order to maintain their working function.

> ‘Every day I use them, because for me it is the most important thing, except when it is raining I don’t use them. I protect them against humidity.’ (M03)

Participants reported that in public spaces the level of background noise was a challenge. In such environments the competing noise and interference distracted from what the participant was specifically trying to hear. Equally, it was reported that loud noises caused ear discomfort. For example, a 68-year-old female reported that with the constant, loud background noise of traffic:

> ‘When I’m on the street and there is too much noise, I need to fix the volume’ (F12)

Similarly, a 67-year-old male reported that in specific circumstances, background noise may inhibit communication:

> ‘Sometimes when there is a radio, or for example if I take the bus and it has music inside and someone speaks to me, then there I am not able to hear any more.’ (M23)

The ability to detect the direction of a sound was identified as a common challenge when wearing hearing aids, specifically when using over-crowded public transport. A 66-year old male describes his experience:

> ‘Sometimes I have problems in locating the noises. For example, when I take the public bus, they are speaking but I’m not able to see where they are coming from.’ (M14

Some participants wore their hearing aids much less frequently, for fewer hours per day due to the nature of their work. For example, one participant worked as a butcher and described some of the challenges with wearing his hearing aids at work:

> ‘I don´t use them most of the time, because I work too much in the water [preparing the meat] and I am afraid I will drop them in the water. I also walk every day to my work, around 6 kilometres for an hour. They [Clinic Foundation] told me that if I sweat I can also get them wet, so I try to avoid using them while I walk.’ (M23)

The key reasons for lack of use were due to concerns over damaging the hearing aids by submerging them in water, the effects of humidity on their working function and accidental loss. Under these circumstances participants were worried that they would not be able to repair their hearing aid or be able to afford a replacement device. In this instance, the reason for restricting their usage was based on the type of occupation and the environmental conditions of the workplace.

In summary this section has identified the key challenges of hearing loss, acknowledging the emotional impact, including experiences of stigma and discrimination. The impact of hearing aids have also been explored, demonstrating a significant improvement in the ability to communicate and interact with other people. Some of the environmental limitations to hearing aid functionality have also be identified.

4.4 The Audiology Clinic Experience

This section of the qualitative analysis forms an evaluation of the audiology clinic and its key activities from the perspective of the interview participant. An adapted UK National Health Service Framework has been applied to provide structure.[183] This information is important for identifying some of the barriers and facilitating factors to hearing aid usage.

4.4.1 Accessing Services

Several participants identified challenges with accessing the clinic due to its geographical location and the associated financial costs. One 67-year-old male described the difficulties he encountered with attending his clinic appointment:

> 'I went to the clinic and there were so many people … they told me the Doctor was very busy and I had to wait, but then I told her [Clinic Receptionist] that I had to leave, and I left. I had to leave because it is very expensive for me, I spent Q200.00 on the person I paid to take me to CEDAF [the clinic], the parking, and then my lunch and his lunch, so I spent around Q300.00. I left because I had to get to work, so they gave me another appointment. But in that time, I was sick because I am also diabetic, and therefore I couldn´t get to the appointment. They called me again and gave me another appointment and I went and they gave me my batteries and set the next appointment.' (M23)

Similarly, a 63-year-old male shared his experience of the journey and use of public transport, citing the geographical location of the clinic as a key challenge and safety concern:

> 'It is kind of difficult [to get to the clinic] due to the distance and the place where it is located in Guatemala City. It is not too

> expensive, but it is dangerous as I need to take a bus to the city.' (M10)

A 39-year-old male echoed these concerns and shared his personal experience and difficulties in negotiating time off work to attend his appointment and access clinic services.

> 'Having to go all the way to the city. We are not too far… but due to my work - I do not have permission to go sometimes.' (M05)

4.4.2 Service Experience

Participants provided a chronological account of their service experience. This included, a preliminary ear-health examination and audiology screening which was undertaken in a community-based outreach clinic, a short distance from where they lived. The screening was followed by a scheduled visit (appointment provided) to a specialist Audiology Clinic based in the medical district of central Guatemala City. Participants explained that their clinic appointment involved a preliminary consultation with an Audiologist and a series of hearing tests. This was followed by the technician taking an impression of their ear and producing an ear-mold. A follow-up appointment involved the testing and fitting of their hearing aids. All participants reported a positive experience and high levels of satisfaction with the hearing assessment and device fitting services they received. For example, a 27-year old female described her experience at the clinic;

> 'They were all very nice to me, from the moment I was fitted, I could hear fine … I just want to say that I feel very happy now because I am able to hear' (F08)

The participants were provided with information on how to care and maintain their devices. The information on hearing aid guidance was appreciated by participants, as described by a 65-year-old male participant:

> ‘It was great, they explained to me how to clean them, put the batteries in, and I also read the manual. I read it from the start to the end’ (M03)

4.4.3 Service Impact

A 39-year-old male recalls his very first experience and his reaction to wearing hearing aids at the Audiology Clinic:

> ‘Hearing aids basically changed my life, I am a different person since I am wearing them… I had a good, first experience, when I had to give some money, pay with the bills, the money made a sound when I counted it … a shhh! shhh! shhh! My wife was with me and I told her - Wow, the bills make sounds, and she said it was normal, but I realized it was normal for her but for me, this was new.’ (M05)

All participants expressed their gratitude, including a 63-year-old male who summarised his experience at the clinic;

> ‘I’m satisfied, comfortable and grateful … a big support’ (M01)

4.4.4 Service Improvement

Ongoing ear health and device support services are currently provided by the Audiology Clinic based in Guatemala City. However, it was acknowledged that such comprehensive public services are uncommon in Guatemala and that the clinic is limited to one, small geographical area. Several participants described how the clinic’s out-reach work could be extended to help people in the community maximise their hearing aid use.

As such, one 55-year old male participant reported on the function and importance of follow-up:

> ‘They are all new experiences, everyone will need a follow up, about the use, care, how to put it on or take it out, so that they can make very good use of it. And all that would contribute to it lasting as long as possible.’ (M15)

In summary, all participants reported that the clinic provided a high quality, professional hearing assessment and device fitting service within a kind and caring environment. Some participants expressed their concerns relating to service accessibility and the geographical location of the clinic. This included the distance from their home, the expense of traveling and parking at the facility as well as the need to navigate unsafe public transport and negotiate time off work to attend their appointments.

4.5 Impact on Significant Others

A quarter of the in-depth interviews were undertaken in the presence of a significant other such as a wife or husband of the participant. While it is acknowledged that this may introduce bias and inhibit some responses from the participant, this provided an informative insight into the significant others perception of hearing impairment and the impact of hearing aids. A total of six significant others including a husband, wife and daughter actively participated in the in-depth interviews.

Most relatives reported that prior to the fitting and use of hearing aids, the hearing impairment had a significant impact on the participant’s life, for example, the daughter of a 73-year old male agricultural farmer describes her father’s social isolation and lack of community participation:

> ‘I am very concerned because he doesn´t go out, he says he doesn´t go out even to funerals, because he can´t hear and is ashamed to ask people to repeat again … He is invited to

> baptisms, funerals, weddings, birthdays, communions but he doesn´t go out.'

Equally, the daughter of a 71-year old male described how her family interpreted and responded to their father's hearing loss.

> 'Every time we speak to him, we needed to shout, my mother, brother everyone, and they felt angry at him because he didn´t pay attention.' (M18: Daughter)

This form of response was common and suggests that the cause and nature of the communication challenge was unknown to the family. This lack of awareness or understanding of the hearing impairment led to the participant's behaviours being interpreted and explained as a poor attention span, lack of concentration or general disinterest. Most significant others reported a positive impact of the case wearing hearing aids and a significant improvement in communication. For example, the daughter of a 62-year-old female describes how communication had improved with her mother being more attentive and both parties having greater understanding of the conversation.

> 'She pays more attention, because before when she asked for something we did not understand each other, but now she can explain better what she needs.' (F13: Daughter)

A daughter describes the positive impact that hearing aid usage has had on her 83-year-old mother, interacting with others and participating in social activities:

> 'My mother is 83 years of age, but she goes to the market, she goes to the mall, to friends, she relates with other people.' (F19)

In summary, significant others and family members are acutely aware of a communication problem, although they may not understand the cause or the extent to which hearing loss has contributed. Through interaction with the

participant the significant others response to these challenges may have a positive impact, for example, in offering support or encouraging the participant to seek help. However, a negative response, expressing feelings of anger, upset and frustration at not being able to fully socially engage, may propagate feelings of disconnection, social isolation and stigma for the case.

4.6 Case Studies

Based on the quantitative questionnaire data analysis and the responses obtained from the in-depth interviews, two case studies were chosen to illustrate the dynamic and complex realities of living with hearing loss and the experience and impact of using hearing aids. Case studies provide added value as they show how factors that determine a specific situation or context are not present in isolation but are interacting and reinforcing. Multi-dimensional factors, from an activity, participatory, personal or environmental domain are combined to form a compound effect on people's lives. These case studies explore the lives of two participants, Marta and Roberto, selected to illustrate a range of cross-cutting issues. To maintain confidentiality, their names have been changed.

4.6.1 Case Study I: Marta

Marta is a 63-year-old female with bilateral moderate hearing loss. She was widowed two years ago and now lives with her daughter and two grandchildren in an urban area of Guatemala City. Marta is not employed in full or part-time paid work outside of the family home. Instead, she stays at home fulfilling housekeeping and childcare requirements which enables her daughter to go out to work and generate a household income. As well as her hearing loss, Marta reports other medical conditions that cause difficulty with walking and climbing stairs. Marta also experiences challenges with her memory and concentration. The daughter reports that since her father has passed away, her mother has been suffering with depression and now rarely leaves the house.

Up until two years ago, Marta did not think there was a problem with her hearing and that she could hear normally. However, over a longer period of time, her family members recall a difficulty with communication and the need for them to

speak louder. Upon reflection, and now using hearing aids, Marta is aware that for many years she could not hear properly and feels angry about her long-standing hearing impairment.

Marta was formally assessed with moderate hearing loss nine months ago and was fitted with bilateral hearing aids to which, like all participants, she contributed $50. Maria's experience of assessment, examination and device fitting at the clinic was very positive and she reports on how she was advised on how to look after her hearing aids. Marta reports that she wears her hearing aids on a daily-basis, for more than eight hours per day. In the daytime, she only removes the devices for an afternoon rest. Since wearing the devices, Marta has noticed a considerable improvement in her ability to communicate, she is able to hear when someone is talking to her and now the volume of the television is much lower. Marta's daughter has also noticed the positive impact and reports that since wearing her hearing aids, she and other family members do not need to speak as loud when engaging in a conversation.

Marta recalls an incident several months after the devices were fitted when they stopped working. Without her hearing aids, Marta was unable to communicate with the clinic on the telephone and was therefore dependant on her daughter to make contact. Marta was invited to attend a community ear-health outreach clinic close to her home, where her hearing aids were successfully adjusted and fixed. There have not been no further challenges or adverse incidents with using her hearing aids, although she does report an intermittent itchy-ness in her ears and the occasional headache. Marta reports that the most significant benefit of using hearing aids has been feeling safer and more confident. Despite the musculoskeletal conditions affecting the joints of her knees and feet, which had previously made her feel unsafe, over the last two months Marta has been able to mobilise and leave the house. Both Marta and her daughter acknowledge that the hearing aids have provided significant help, as she is now able to hear the traffic and safely walk in the street.

This case study shows that for an unknown, long period of time, Marta had been unaware of her hearing impairment whilst her family members were experiencing an increasing difficulty with communication and had to adopt compensatory behaviours such as speaking louder. It is also recognised that hearing loss may be one of several co-morbidities or personal situations which may jointly impact on an individual's quality of life to a varying degree. In this case study, the provision of hearing aids is thought to have improved Marta's ability to communicate, made her less dependent on family members and enhanced her emotional wellbeing. This intervention has also contributed to her ability to safely leave the house and socially participate, which may help to improve her physical health.

4.6.2 Case Study II: Roberto

Roberto is a 66-year old male with bilateral, moderate hearing loss. Roberto lives with his large, multi-generational, extended family in a rural area on the outskirts of a large town. Roberto currently works full-time as a car mechanic and vehicle painter and as such contributes to the household income. As well as his hearing loss, Roberto also reports difficulty with his eyesight, with walking and climbing stairs.

Roberto's hearing loss had a gradual onset and over the last few years has caused him difficulties with communication. He recalls that on several occasions, if he was at home with several members of his family and they were all speaking simultaneously, he could not understand the conversation and was unable to share and contribute to the family discussion. In response, he would leave the room and retreat to his bedroom. Roberto explained that his wife had noticed this behaviour and had assumed that he was avoiding family discussions and time together, concluding that Roberto did not love or care about his wife and family anymore.

Roberto was fitted with hearing aids eight months ago and now wears them on a daily-basis. Roberto reports that with the use of hearing aids he is now able to share and contribute to family conversations, improving his inter-family relationships.

As a car painter and mechanic, Roberto reports that he does not wear his hearing aids within the garage environment of his work due to the uncomfortable loud noises, requiring protective ear plugs to be worn and the use of aerosol paint which may damage the devices. In total, Roberto reports that before and after work, he wears his hearing aids for approximately six hours per day. Roberto also reported difficulty with sound location when using his hearing aids, especially on the public bus or when walking in the street, if a car is coming he is unable to hear which direction it is coming from. He acknowledges that this carries potential safety and security risks. Roberto is able to compensate by taking extra time and care to observe the traffic. Roberto reports that he maintains and cares for his hearing aids and when not in use or overnight, stores them in a de-humidifying container which he purchased at the clinic. Overall, Roberto is very pleased with his hearing aids and after not being able to hear properly, the positive impact they have had on his life. He acknowledges that due to his limited resources, he could not have afforded the hearing aids without the support from the clinic.

This case study demonstrates the impact that hearing loss can have on a significant other, such as the wife or husband. It also identifies the associated responsive behaviors of participants and the adverse effect on family relationships and dynamics. The challenges of using hearing aids at work were also explored, identifying occupational hazards and environmental conditions where device usage was compromised. Equally, it is acknowledged that under such working conditions, maintaining a safe working environment with effective hearing, is also an important consideration.

4.7 The Researcher's Personal Reflection and Positionality

This section of the qualitative results chapter provides an account of the research project journey and critically reflects on the role and experiences of a researcher with hearing loss, the same sensory impairment as that of the research population. Set within a contrasting socio-economic, cultural and linguistic environment, the practical challenges of conducting fieldwork as a hearing-impaired researcher are considered, the academic implications examined and the positive and negative contributions that such inclusive research may provide are explored. The underlying themes and core elements of this reflective account were written by the author (Mark Spreckley & Hannah Kuper) and published in the Knowledge Management for Development Journal in 2016.[184]

I was unaware that I had a hearing impairment. It was initially detected by friends and family who were concerned that I liked the volume of my music or the television very loud. I reluctantly made an appointment for a hearing test and following an examination and assessment, was advised that at the age of 42 that I had a moderate-severe bilateral hearing loss. A follow-up consultation with an ENT Specialist and MRI scan confirmed the assessment outcome to which the cause or origin was unknown or idiopathic. I now wear bilateral in-the-ear devices every day and receive annual hearing assessments.

As the Project Manager, my role was to appoint, train and manage a team of fieldworkers who conducted face to face interviews and hearing tests with participants across urban and rural areas of Guatemala. I coordinated and operationally managed the team activities, project resources and stakeholder communications and was assisted in these duties by an experienced Spanish translator. I also conducted in-depth interviews with adults diagnosed with moderate-severe hearing impairment. During the project fieldwork, I was engaged in a series of activities which required effective communication with key stakeholders. These activities were undertaken under a broad range of environmental conditions. Such interactions included, learning Spanish within a language school, teaching research methodology within a classroom setting,

supporting and guiding the team of fieldworkers and conducting in-depth interviews within participant homes.

As a researcher with a hearing impairment the most significant fieldwork challenge was the physical environment. Internal and external high humidity levels affected my in-the-ear hearing aid functionality and caused intermittent device failure. By acting as a physical obstruction and ear plug, conversational amplification was further reduced. During the interview process I had to discretely remove the device and the translated conversation volume was reduced to a whisper. Equally, I found that background noise within participant homes, such as the television and concurrent family member conversations provided unwanted competing noise amplification and distraction. Under such circumstances, my usual compensatory response is to lip read and use non-verbal visual cues. However, due to the language barrier and required parallel side-seating configuration of the translator, this was a challenging experience.

Despite these environmental challenges, by discussing these experiences and working in collaboration with the translator, practical compensatory behaviours and physical adjustments were introduced. For example, to maximise amplification and assist with lip reading, seating re-configuration enabled me to be in close-proximity to the translator and within their line of sight and where appropriate, background noise was controlled by communicating with family members. In contrast, from a wider societal perspective, the prevalence of poverty, political corruption and limited social infrastructure in Guatemala equates to a reputation for gang related violent crime and robbery. Under these environmental conditions, whilst travelling and working within most areas of the country we adopted a range of personal safety and security measures.

These were universal precautions, recommended for all, however, with my sensory impairment that affects spatial orientation and my ability to hear, such vulnerabilities require heightened awareness and situation avoidance tactics to be employed. For example, repetitive and cautious observations with crossing the road, avoided walking at night in unfamiliar safe areas or in streets which had vehicle access and no footpath.

Conducting interviews with participants that have a hearing impairment was a challenging experience. Interviews of a longer duration were necessary to fully capture the views of the participant with hearing loss and there was often a greater reliance on family members for communication, which made it more difficult to elicit the specific views of the individual. These challenges were magnified by my own hearing impairment. However, despite the language barrier, my own introductory disclosure of hearing loss and use of hearing aids, helped to provide a relaxed, open setting from which to draw upon my own experience and ask personal, sensitive questions related to such themes as family relationships, work and mental health. Furthermore, my own use of hearing aids demonstrated my personal interest, understanding and long-term project commitment, and helped to build a rapport with the interviewees. I believe this contributed to a greater richness of the data collected.

As someone with close association and personal experience of hearing loss, it is recognized that my involvement in the interview process may prejudice the research results. For example, I may assume that with the existence of background noise, all participants experience communication difficulties. Such assumptions may be formulated by me, based on my experience and may not be representative of the situational reality. Such unconscious bias may misrepresent the impact of the disability and provide an exaggerated account or potential under reporting.

In this research study, such research bias was managed and controlled as far as possible by introducing a range of measures such as pre-formatted and structured question sets, recorded and transcribed in-depth interviews that were analysed thematically largely through pre-determined codes, and fieldwork awareness training. My perception was that my working relationship with the fieldworkers was improved by sharing my personal experience of hearing loss. The ability to respond to fieldworker questions and openly share my experience, transcended cultural and language barriers and reinforced research credibility and motivation as well as cultivating mutual understanding and respect. Despite these practical, field-based challenges and academic considerations, this research project has also enabled significant, positive contributions to be identified.

The benefits of inclusive research may be demonstrated in the planning and preparation phase of the project, whereby my background knowledge and personal experience could help me in the composition, structure and formatting of the research tools. The methodological decision-making process can be informed by knowing what questions to ask and why. For example, based on my own experience, a specific question that was included in the questionnaire was 'At home or at work, how often has your hearing problem potentially caused or contributed to a safety or security concern? Please explain what happened?' Such inclusion ensures that the research tools reflect the dynamic and real-life stories of the target population, eliciting rich and meaningful data that positively contributes to the research aim and objectives. I was also particularly interested in including measure of the impact of significant others, as I am aware that in my own life my partner and family are affected by my hearing loss.

As a researcher, when conducting in-depth interviews, one is always aware that you might be told only what a respondent thinks you want to hear. However, by informing the participant that I too, shared a similar hearing impairment, they were potentially persuaded of my empathy and deeper understanding of their situation. Such disclosure was met positively with eye contact, openness, a sharing of situational examples and rich in-depth responses.

In summary, during the fieldwork components of this research project I encountered a broad range of practical challenges due to my hearing impairment. These included the effect of environmental humidity on hearing aid function, communication constraints and the impact on personal safety and security awareness. I tried as far as possible to be aware of the academic and professional implications of my personal situation and the impact of disability disclosure and researcher bias. However, my personal experience of hearing loss and the use of hearing aids also helped me throughout the planning and implementation phase of this research project. Shared knowledge and experience enhanced the design of the research tools, led to greater openness at interview, aided stakeholder communication and facilitated data interpretation and analysis. For the future, a deeper analysis of this shared understanding and language between the researcher with a hearing impairment and the participants could be explored

5. Discussion

The objective of this research study was to investigate the impact of hearing impairment and provision of hearing aids on poverty, activity participation, mental health and quality of life of an adult population living in Guatemala.

The preliminary section of the discussion provides a summary of the key findings and compares and contrasts the data obtained from the quantitative structured questionnaire analysis with the outcomes from the qualitative in-depth interviews. Based on the collective research outcomes, the barriers and facilitating factors to intervention are identified. The conceptual Theory of Change framework and research outcomes are reviewed in the context of the existing academic body of knowledge. This section is followed by the strengths and limitations of the research methodology being explored. Areas of further research and recommendations for strategic planning, resource management and service provision are then proposed. The research study conclusion is followed by a reflective, personal account of the authors journey as a Doctor of Public Health Candidate.

5.1 Key Findings

5.1.1 Impact of hearing Loss

This impact study compared 180 adult cases with audio-metrically assessed moderate to profound hearing loss and 143 age and sex matched control participants with confirmed ‘normal’ hearing or mild, non-disabling hearing loss. A structured questionnaire was administered at baseline including assessment of poverty, mental health, activities, and quality of life. Case participants were then assessed and fitted with hearing aids. After a post-intervention mean period of 7.5 months, cases and controls were re-interviewed and the follow-up data compared with baseline. Twenty-two in-depth qualitative interviews were undertaken with cases during the post-intervention phase of the project.

At baseline, compared to controls without disabling hearing loss, individual earnings as well as household and per capita expenditure were significantly lower for cases, indicating that cases were poorer than controls. Cases spent less money on household items, home repairs and maintenance, as well as sources of entertainment. No differences were detected in asset ownership. Cases spent more time performing household tasks but did not differ in other activities.

Although over half of the cases were retired and not engaged in full time employment, the remaining proportion of cases were involved in work activities such as hospitality, farm labour and healthcare administration. Analysis of the in-depth case interviews showed that these forms of employment most frequently required cases to socially interact and regularly communicate with co-workers and customers in order to hear instructions, participate at meetings and fulfil customer orders. Hearing loss affected their perceived performance at work. Most participants described how their hearing impairment challenged their ability to understand what someone else was saying, reporting that other people's voices sounded too low, muffled or unclear and that they frequently missed all or part of a conversation. Such communication challenges may have influenced educational attainment and the type and level of work that the cases could perform and thereby affected their income potential. In addition to posing communication challenges, hearing loss appears to impact work by undermining their performance by necessitating compensatory actions. Using these inappropriately or mistimed, had a detrimental effect on how they were perceived by customers or co-workers who would often question their level of competence, understanding and ability to perform their role.

Participant experiences of hearing loss and its associated challenges, frequently generated a behavioural response such as, a self-imposed withdrawal from a social situation or limited participation or avoidance of activities involving communication such as using the telephone. This was corroborated by quantitative data that identified cases as having a poorer quality of life across a range of domains, but not in overall quality of life. The qualitative data identified some of the ways in which they attempted to conceal or compensate for their hearing loss, through their own compensatory actions such as by physically

repositioning themselves to hear more clearly, using visual cues or lip reading or by recruiting an assistant to help interpret or communicate on their behalf. Cases felt ashamed or embarrassed of their inability to communicate, their dependency on other people and how hearing loss affected their interpersonal relationships.

The quantitative data demonstrated a positive association between cases and their experience of depressive symptoms. Most participants expressed their concern about how other people perceived and responded to their communication challenges. Any negative verbal or behavioral response affected how they felt and was expressed in words such as ‘sad, embarrassed, ashamed and uncomfortable.’ The emotional and social impact of hearing loss was rated as a significant disability by almost half of the cases and was rated even higher by their significant others.

The qualitative data demonstrated that significant others and family members are acutely aware of and have primary experience of the communication challenges, although they may not know the cause or the extent to which hearing loss has contributed. Through interaction with the participant the significant others response to these challenges may have a positive impact for example, in offering support or encouraging the participant to seek help. However, a negative response, expressing feelings of anger, upset and frustration at not being able to fully socially engage, may propagate feelings of disconnection, social isolation and stigma. Analysis of the significant other data suggests that case participants may have under-reported the impact of their hearing loss. It could be inferred that the ‘hidden’ impact of hearing loss on quality of life and mental health may therefore be much greater.

5.1.2 Impact of Hearing Aids

At follow-up, over 70% of cases reported using their hearing aids on a daily basis of which over three quarters (78%) used them for at least four hours per day. For cases that attended a follow-up appointment (84%), actual hearing aid usage data (downloaded from the device) showed that 98% of cases used their hearing aids for at least 1-4 hours per day.

During the in-depth qualitative interviews cases provided multiple reasons or justification for limiting the use of their hearing aids and not wearing them all of the time. These limiting factors included their physical capability to fit and put the hearing aids on to conserving battery power by only using the devices at pre-planned social events, driven by the financial cost and affordability of replacement batteries. At work the key reasons for a general lack of use were due to concerns over damaging the hearing aids by submerging them in water, the effects of humidity on their working function and the risk of accidental loss.

There was no significant change in employment status for either case or control groups at follow up. There was also no change in the proportion of people looking for work. However, it is possible that hearing aid acquisition did not increase employment in this group of predominantly older people but may have improved their performance or quality of the work experience.
For example, cases recognised that prior to using their hearing aids, greater effort and concentration was required to listen and understand a conversation. The qualitative data analysis suggests that the use of hearing aids reduced the amount of effort required to complete a task. This enabled the participant to effectively perform their role and responsibilities in full and in the long term, may contribute to greater job satisfaction and security.

Household income increased among the cases between baseline and follow-up, but not among the controls. Individual income fell among the controls at follow-up as compared to baseline but remained similar for cases. There was no significant change to case participant's per capita expenditure at household or individual level. By contrast, for the control group at follow-up there was a substantial decline in both the level of household and per capita income and expenditure.
External factors such as national economic uncertainty, political fragmentation, reduction in public investment, and insufficient GDP growth may provide an explanation for these results, inferring that under more favourable economic conditions, case income and expenditure at follow up may have increased and that the use of hearing aids were buffering and protecting the cases from the economic losses experienced among the controls and the decline in living

standards occurring in Guatemala.[185] At follow up the allocation of per capita expenditure for cases and controls was similar.

At follow up there was no change in asset ownership among cases or controls. It is acknowledged that the acquisition of such high value products may take longer, with purchases essential to daily living such as food, being prioritised. Longer follow up may also be required to ascertain an impact of hearing aids on reducing poverty, particularly in terms of accumulating assets. Compared to baseline, cases demonstrated a significant reduction in time spent participating in household tasks.

Although the population size was small, there was a reduction in the number of cases reporting symptoms of depression. At baseline, 27% of cases reported depressive symptoms (minimal-severe), which reduced to 16% at follow-up. By contrast, among controls there was no change in depression prevalence, and a small reduction in depressive symptoms. Qualitative data captured how participants felt about wearing hearing aids and the positive impact that this intervention has had on their psychological wellbeing and mental health, with several respondents commenting that they felt 'safer, happier, satisfied and had greater understanding.' The factors that may have changed in the 6-9 month period between hearing aid fitting and the follow-up interview, which may have contributed to an improvement in mental health are the specific mechanisms associated with the Theory of Change including, the ability to hear and communicate, leading to social inclusion, activity participation and increasing access to education and employment. Other factors such as the effect of prescribed medication, i.e. anti-depressants, provision of counselling, the effective management of other medical conditions, or increased family and significant other input and support may have also contributed to an improvement in mental health over this time frame.

At follow-up there was a significant improvement in quality of life of cases across all domains, except for social relationships. Despite some specific domain changes, there was no change in overall quality of life among the controls. 88% of case participants reported that hearing aids had positively changed their

enjoyment of life. They reported that the use of hearing aids had significantly improved their performance in a range of daily activities and reported specific factors that contributed to their perception of safety and security including an enhanced sensory awareness of the environment and the ability to hear oncoming road traffic or people.

As for hearing aid experience, cases reported that the most significant benefit of wearing such devices had been the ability to communicate with family and friends (56%) and the vast majority (86%) reported that hearing aids had improved their self-confidence. A high level of satisfaction with amplification in daily life scores were recorded across all sub-score domains.

The 'Hearing Handicap Inventory for Adults' mean scores for cases at follow up showed an increase in reported difficulties, with 91% of all cases reporting a significant level of disability at follow-up as compared with 49% at baseline. The possible reasons for this unexpected result may include a lack of understanding or misinterpretation of the post-intervention question set and scoring mechanism, for example, retrospectively, reporting on the impact of hearing loss before intervention, instead of reflecting on their current, improved hearing function. Alternatively, these responses may reflect disappointment or frustration after high expectations of hearing aid function are not met. A poor experience of hearing aids and/or incorrect fitting or usage may also contribute to these unexpected results. Negative feedback from a significant other may also contribute. These proposed explanations and other contributory factors require further exploration.

In summary, these collective methodologies have provided greater insight and understanding of the impact of hearing loss and the provision of hearing aids within this specific population. The qualitative analysis has helped to provide a detailed interpretation of the quantitative data.

5.2 Research in Context of Existing Academic Literature

This section aims to provide an explanation of the results in the context of the academic literature and current body of knowledge, with the caveat that existing data is relatively sparse, in particular from Low and Middle Income settings, as described in the introduction. The Theory of Change conceptual framework and its constituent elements are reviewed for accuracy and completeness and any gaps in coverage are identified.

This research study reported that case participants with disabling hearing loss were significantly poorer than the control group, as measured by expenditure and were less likely to be in paid employment. A recent systematic review of 150 studies from LMICs found strong evidence for an association between poverty and disability in general, and also between poverty and sensory impairments more specifically.[186] The relationship between poverty and hearing impairment is likely to be bi-directional. People who are poorer may live in environments conducive to hearing loss (e.g. high rates of infection, high levels of occupational noise exposure) and/or less likely to have hearing aids when needed.[45]
At the same time, people who have hearing loss may become poorer, for instance due to reduced levels of employment or earning levels.[78]
The figures on employment generated in this study are similar to an Australian study which demonstrated that hearing loss was associated with an increased rate of non-participation in employment of between 11 - 17%.[80]
This study demonstrated that cases with hearing loss ranging from moderate – profound had earnings which were 35% significantly lower than the control group. Similarly, a study conducted in the USA reported a 50-70% earnings gap amongst people with severe to profound hearing loss as compared to their non-hearing impaired peers.[83]

At baseline, expenditure on food was similar across the two groups, however cases were spending more on healthcare and less on education. This finding may imply that due to the prioritized health expenditure, children in families of people with hearing loss were receiving less education and so that could result in an inter-generational transfer of poverty. In this way, a disability such as hearing

impairment can create poverty in the next generation or prevent its escape, operating as a cycle, because of barriers to education and employment.[187,188,186]

The literature shows that there is a high prevalence of mental health problems in people who are deaf or hard of hearing.[189] However, the research is predominantly from high income countries and literature on the impact of hearing loss and the use of hearing aids on mental health in LMIC's is relatively sparse. The results from a large scale postal survey in Norway, demonstrated that there was significantly more symptoms of anxiety and depression in individuals with a hearing impairment as compared to a hearing sample of respondents.[190]
The study suggests that these symptoms may stem from childhood or be attributed to the different etiologies of deafness, socioeconomic issues, or different experiences related to stigma and discrimination. Similar to the results observed in Guatemala, a study conducted in the USA reported that depressive symptoms were common in older adults with bilateral hearing loss.[191]

The literature also suggests that the mental health condition or symptoms associated with a hearing impairment may vary. For example, it has been reported that the prevalence of drug/alcohol-use disorders may be higher in people with hearing loss.[192]
A large Korean study reported a higher incidence of stress in females with a hearing impairment, depressive symptoms in older males and an association of hearing impairment with suicide ideation in older females.[193] A research study conducted in Nigeria reported that hearing loss in elderly patients had a negative effect on their activities of daily living and functionality, especially within the emotional domain, representing depression.[194] The results of this study were also reflected in a large study conducted in the USA, in which the impact of hearing loss on quality of life in older adults was investigated.[71] The study reported that participants with moderate to severe hearing loss were almost eight times as likely as those without hearing loss to have self-reported difficulties with communication and concluded that severity of hearing loss is associated with reduced quality of life in older adults.
In comparison, a research study in Yemen used an adapted version of the Hearing Handicap Inventory for Adults question set and demonstrated an

association between hearing loss and decreased quality of life.[91] By applying a similar question set this study demonstrated a disability in 78% of all cases and a significantly 'high' level of disability in over half (53%) of all cases.

The post-fitting support clinic was attended by 88% of cases in the Guatemala study. During this visit objective usage data was downloaded from the hearing aid and analysed. It was identified that all cases (100%) had used their hearing aids since being fitted and 98% had used their devices for an average of four hours per day. In comparison, the academic literature suggests that the number of people who are given a hearing aid and who do not wear them ranges from 5%[195] to 24%.[130,196] It is also reported that between 1% and 40% of all hearing aids dispensed, are never or rarely used.[197]

The high-level usage rates observed in this Guatemala study may be attributed to a multi-dimensional management strategy employed by the Sonrisas que Escuchan Foundation which aims to maximise device usage and auditory benefit. This strategy is based on each case participant contributing to the subsidized cost of their devices and aural rehabilitation services, demonstrating their commitment to the hearing aid usage. In return, they are provided with a high-quality hearing aid, accompanied by a comprehensive assessment, fitting service and access to regular (monthly) ongoing device maintenance and supportive clinic visits. This ear health management programme may be the reason for the high level of aid usage, however further research is necessary to investigate and determine the specific role and contribution of each element.

At follow-up, case participants had shown significantly improved quality of life, however, not within the social relationship domain. This domain specifically relates to personal relationships, intimacy and support from friends and the limited follow-up period, opportunity and inclination of an older population to develop social relationships may explain the lack of impact within this specific domain.

The majority of cases (88%) reported that hearing aids had positively changed their enjoyment of life. Similarly, a study conducted in Brazil reported that effective use of hearing aids improved communication, which made it possible for

elderly individuals to reassume their family and social interactions, thereby improving their quality of life.[131] In this study, case participants reported significantly fewer symptoms of depression at follow up and of those who reported moderate to severe symptoms of depression at baseline, there was an 83% reduction at follow-up. Similarly a small study of elderly people conducted in Turkey found a decrease of depressive signs and an increase of cognitive functions after using hearing aids.[132] In a large cross-sectional study of UK adults, hearing aid use was associated with better cognition and improved quality of life.[98] A high level of satisfaction with amplification in daily life across all sub-score dimensions was recorded. These scores are consistent with previous research in the US and a large Australian study of older adults.[167,198]

In contrast, previous US and European studies using other self-report questionnaires have demonstrated a wide variance in satisfaction ratings, from 50% to more recent studies reporting satisfaction ratings from 68% - 80%[168,198, 200] The importance of these ratings are that satisfied hearing aid users are often frequent users and sources of referral for other people with hearing impairment.[84] The current results from Guatemala therefore show relatively higher levels of satisfaction than in previous studies. Finding reasons for high levels of satisfaction is currently speculative and will require further exploration.
In summary, due to the lack of research studies conducted in LMIC's, comparisons with high income settings are cautiously applied.

5.3 Theory of Change Review

For the key elements of the Theory of Change to appropriately lead to the impact, or goal of the ToC, the constituent activities and assumptions, including their relationship to the time-scaled outcomes, need to be accurately identified and clearly described.[201] For the purposes of evaluating the Theory of Change, three specific quality control criteria have been identified, these address plausibility, feasibility and testability.[202]

The plausibility of the framework refers to the logic of the outcomes pathway; Do they make sense, are the outcomes in the right sequence, and are there any

gaps? Are any pre-conditions necessary and collectively sufficient to reach the long-term outcomes and impact?

The assumptions that underpin the Theory of Change in this study are based on the case and control inclusion criteria and selection processes. The impact and sequential outcomes which form the foundation of the Theory of Change were based on an academic literature review and stakeholder mapping exercise.

In this study, the hypothesised long-term outcome and ultimate impact of hearing aids is to improve access and performance at work thereby enabling increased income, improvement in socio-economic status and a reduction in poverty. These outcomes form a logical sequence. However, as the post-intervention duration and experience of using hearing aids was limited to 7.5 months, not all these long-term changes were observed or recorded in the study. It is proposed that the financial means to improve housing conditions and asset ownership are likely to take much longer and therefore the timescales identified in the original theory of change model have been modified from a mid-term outcome to a long-term outcome to reflect this expectation.

A second hypothesised impact is in improved quality of life. Although quality of life could be enhanced by socio-economic improvement, it was also shown to be independent of these financial measures and associated with other outcomes such as the improvement in communication, social interaction and activity participation. Therefore, in the revised Theory of Change (see figure 53) quality of life has been included across all outcome time-frames.

The feasibility of the Theory of Change refers to whether the intervention can realistically achieve its long-term outcomes and impact, for example, are there adequate resources? Does the scope, expectations, or timeline of the theory need adjustment?

In this study, the ultimate impact is dependent on the short and mid-term outcomes being achieved, these act as precursors and are essential for Theory of Change progression. For example, communication is improved as a short-term outcome and this has a positive influence on family relationships.

As a mid-term outcome, this enhanced social engagement enables greater activity involvement and community participation. However, the key feasibility

issues are the time frame which may have been too short to measure the impact on poverty. Also, as this study was based on an older population, it may have been less feasible to observe an impact on work and therefore poverty. In this context, expectations of the ToC may have been unrealistic.

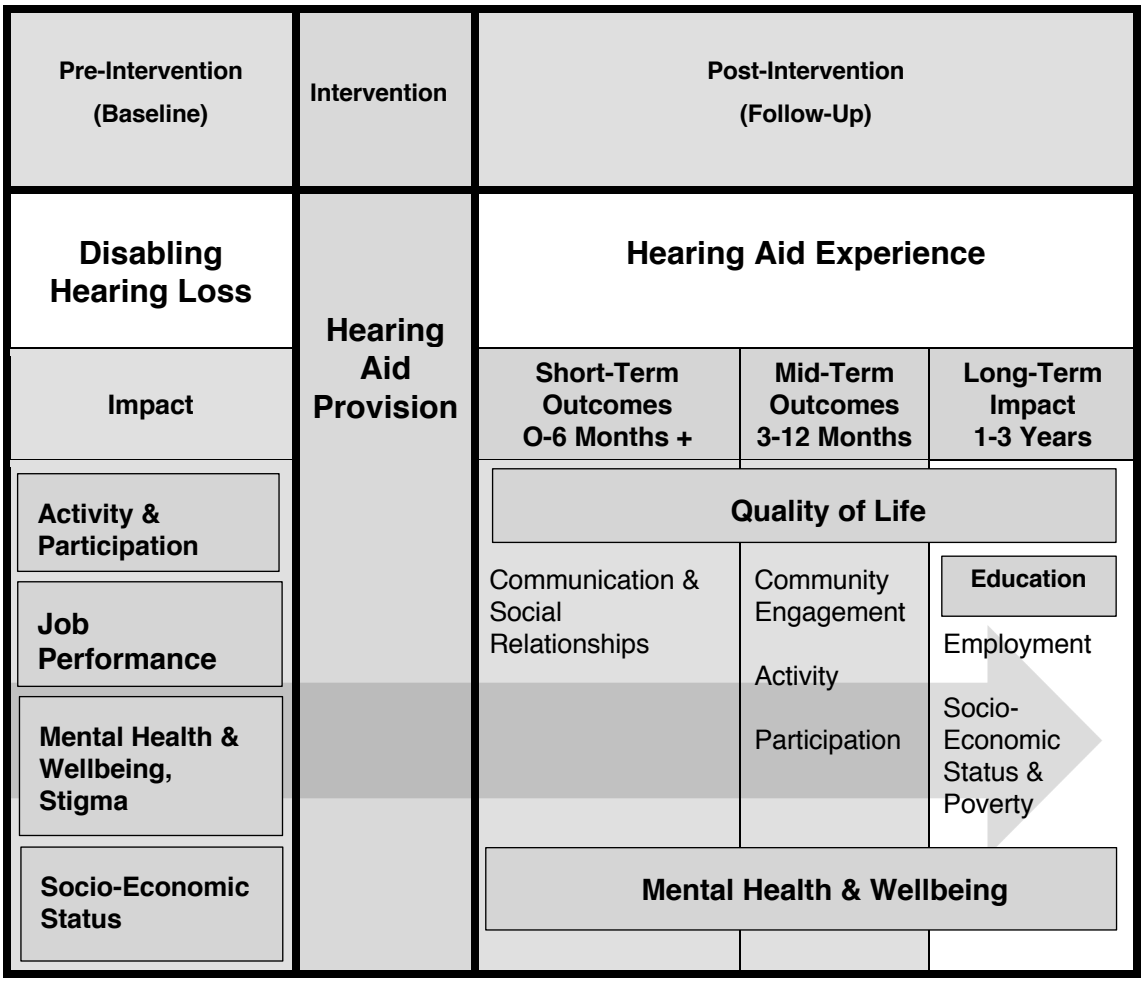
The testability of the Theory of Change refers to what indicators are used to assess and determine an accurate theory of change? Are these indicators measurable and will they facilitate further evaluation of the Theory of Change and determine areas for improvement or further research?

Comprehensive and standardized measures of poverty, quality of life and activities were included in the study at baseline and follow-up. The impact of hearing loss and the use of hearing aids on educational opportunity and performance were not measured and therefore their contribution to the Theory of Change is untested.

Symptoms of depression were measured at baseline and follow-up, however other determinants of mental health, including self-esteem, confidence, stigma and measures of cognitive function were not included. To capture the impact of such elements within the Theory of Change model, a broader and specific range of mental health measures may be required.

In conclusion, the Theory of Change did provide a reasonably accurate, sequential framework, that worked in practice. However, adjustments to timescales, expectation management and context-specific (age and environmental) assumptions were required.

Figure 53: Revised Theory of Change



5.4 Hearing Aid Uptake

The primary clinical intervention for people with hearing loss is hearing aids. However, 80% of adults who may benefit from a hearing aid, do not use them and many people who are provided with a hearing aid do not wear it.[130,203] Within the context of this study based in Guatemala and the wider implications for other LMIC's, it is therefore necessary to identify the factors that affect compliance with this treatment recommendation. The results of this research project and the associated review of the literature have identified the following barriers and facilitating factors to an effective intervention.

5.5 Barriers to Hearing Aid Uptake

5.5.1 Lack of Awareness & Perceived Need

Many people who would benefit from wearing hearing aids do not know that they have a hearing impairment or that treatment is available, and so do not seek help. Some people may consider that they do not require hearing aids as they are socially isolated and do not engage in regular communication.

5.5.2 Financial Cost

Many people cannot afford hearing aids, particularly since they are more likely to be poor. The initial cost of the devices may be prohibitive as well as the associated and ongoing maintenance costs, such as batteries and cleaning materials. Repair or long-term replacement costs also need to be considered.

5.5.3 Clinic Access & Location

Knowing where to get help and the location of the clinic in proximity to home are important considerations. The majority of cases did not have their own means of transport, such as a car or bike and were reliant on public transport or a family member to drive or escort them to the facility. Some cases were unable to independently locate and travel to the city due to safety and security concerns. Due to the long distance, factors such as the cost of fuel, parking and required time off work were prohibitive.

5.5.4 Influence of Significant Other

If the significant other such as the wife or husband does not support or encourage help seeking behaviours or assist with device fitting and maintenance the individual will be reluctant or unable to wear the devices.

5.5.5 Environment

Hearing aids may not be worn due to the environmental conditions and the poor benefit or side effects of using the devices in such conditions. For example, as reported in this research study, excessive humidity or moisture may prevent the devices from working and background noise may cause interference and amplification distraction.

5.5.6 Personal Factors

A common misconception is that the amplification of sound corrects for hearing loss in the same way eyeglasses can do for correctable vision problems.[18] Although making sounds louder to improve audibility is important, older adults may not tolerate too much amplification and frequently describe amplified sounds as being louder, but not necessarily clearer. In older people, loss of manual dexterity in the hands, due to degenerative conditions such as arthritis may cause difficulty in fitting the hearing aid and changing the battery. As found in this study, if the hearing aid user cannot properly insert, remove, and manipulate their hearing aids or constantly require assistance, they are less likely to wear them.

5.5.7 Stigma & Discrimination

A potentially important issue that could affect impact of hearing aids as well as barriers to their use is stigma. This was not explored specifically in the quantitative data, however was frequently flagged as an important issue in the qualitative, in-depth interviews.

Stigma is a prominent feature of many disabilities, chronic diseases and health problems throughout the world and is typically characterized by exclusion, rejection, blame or devaluation that results from experience, perception or reasonable anticipation of an adverse social judgment about a person or

group.[204] In Table 54 the most commonly used terms in contemporary stigma research are defined.

Table 54: Definition of Stigma and Associated Terminology[205]

Term	Definition
Stigma	A deeply discrediting attribute; mark of shame; mark of oppression, devalued social identity
Stigmatization	A social process embedded in social relationships that devalues through conferring labels and stereotyping
Labels	Officially sanctioned terms applied to conditions, individual, groups, places, organizations, institutions, or other social entities
Stereotypes	Negative beliefs and attitudes assigned to labelled social entities
Prejudice	Endorsement of negative beliefs and attitudes in stereotypes
Discrimination	Behaviours that act to endorse and reinforce stereotypes, and disadvantage those labelled

Different forms of stigma may be identified, dependent on its nature and who is involved. These forms of stigma include, *self*-stigma which is internalised acceptance of stereotypes and prejudice, *courtesy* stigma which is discrimination by association with marked groups, *public* stigma which are negative beliefs, attitudes and discriminating behaviours which are endorsed by the general population or *structural* / institutionalised stigma which is prejudice and discrimination by policies, laws, and constitutional practice.[205]

Stigma regarding hearing loss and hearing aids is well documented and known to present a substantial challenge.[4,206] Stigma can manifest itself in many ways, for example, as ageism, the association of hearing loss with old age, vanity and the fear of unattractiveness in relation to hearing aid use and an association with negative stereotypes such as cognitive decline.[4]

A scoping review of the literature on stigma and hearing loss among older persons was conducted by the Department of Community Mental Health, University of Haifa, Israel.[206] Research published between 1982-2014 was reviewed and twenty-one relevant publications were identified.

Conceptually, the studies concentrated on exploring the meaning and subjective experience associated with stigma, especially public and self-stigma. The majority of the studies were based on a description of stigmatizing attitudes and stereotypes associated with hearing loss and hearing aids. The size and visibility of hearing aids were the main features associated with the reluctance to use the devices and with the stigma associated with them. As demonstrated in this study, people who present with hearing loss are often perceived by others to be cognitively diminished, less able, and socially incompetent.[207]

In a study which aimed to understand how stigma impacted upon the help-seeking activities of adults with an acquired hearing loss, it concluded that in order to avoid being identified as a member of a stigmatized group, individuals with hearing loss may choose not to seek health services or fail to comply with recommended treatments.[207]

A previous qualitative study explored the dimensions of stigma experienced by older adults with hearing loss.[208] This longitudinal study conducted interviews over a period of one year with couples, such as a husband and wife. One partner had been audio-metrically assessed with hearing loss and had not previously worn hearing aids. The data was analysed using grounded theory and constant comparative methodologies.

The results indicated that perceived stigma influenced decision-making processes at multiple stages, from the initial acceptance of hearing loss, to the decision of whether to be tested, type of hearing aid selected and when and where hearing aids were worn. Stigma was related to three interrelated experiences, alterations in self-perception, ageism and vanity. Stigma was influenced by partner relationships and external societal forces, such as health and hearing professionals and the media.

The outcome of the study suggests the need to de-stigmatize hearing loss by promoting its assessment and treatment as well as emphasising the importance of remaining actively engaged to support positive physical and cognitive functioning.[208]

There are some emerging consistencies in the factors associated with adult hearing aid usage. In a previous scoping study and a systematic review, the potential reasons for non-use of hearing aids were examined.[130,203] The results showed a broad range of reasons including, stigmatization, under-estimation of hearing loss, hearing aid value, fit and comfort, device maintenance, the individual's personality and attitude, cognitive and functional restrictions, financial affordability, psycho-social, situational factors, healthcare professional's attitudes, ear health and appearance.

The study concluded that one of the most important considerations was the hearing aid value, defined by the level of perceived benefit and comfort. The study also suggested that some of these factors may be modifiable, such as self-perceived loss and stigma and therefore these should be explored further.

In summary, by identifying factors that affect hearing aid usage, appropriate rehabilitation strategies which ensure greater use of hearing aids may be devised and implemented.

5.6 Facilitating Factors to Uptake of Hearing Aids

The facilitating factors to hearing aid usage which were observed in this study are described below. These factors collectively improved uptake and adherence to hearing aid use.

5.6.1 Hearing & Ear Health Screening Provision

The audiology clinic and its public outreach services for adults and children, provided hearing and ear health screening and promoted awareness and understanding of the impact of hearing loss to the wider community. These services were provided by a qualified and experienced audiology team. Where appropriate, a comprehensive follow-up service was provided including, clinical diagnosis, assessment and financially subsidised access and referral for medical

ENT treatment and/or amplification management. These services collectively contributed to improved uptake and adherence.

5.6.2 Integrated Aural Rehabilitation Programme

Amplification and hearing aid provision was complemented by active participation in an ongoing and comprehensive aural rehabilitation programme. Such a holistic programme incorporated device maintenance, expectation management and communication workshops. Access to informal counselling services provided an opportunity to discuss relationships, stigma and coping strategies.

5.6.3 Accessible Audiology Clinic Services

The outreach clinics provided screening, ear health assessment and aid fitting and maintenance services. These were delivered within the local community, were easily accessible, in a convenient, high profile location and with adequate public transportation links.

5.6.4 Financial Support

Due to the high cost of devices and batteries, the provision of subsidized hearing aids and access to maintenance and repair services may have contributed to improved usage. A single payment of $50 seemed to have assigned product value and promoted responsibility and self-help. Further research and modelling is recommended to investigate this theory and to ensure an appropriate financial level is set.

5.6.5 Contribution of the Significant Other

The significant other such as a husband or wife may provide emotional support, promote help-seeking behavior as well as provide practical assistance with verbal and compensatory interactions, clinic appointment and diary management and active participation in aural rehabilitation counselling and communication exercises. Some of these behaviours were actively observed in Guatemala and are reported in the academic literature.[209, 103]

5.7 Research Study Strengths

This section of the discussion reviews the strengths of the design, planning and implementation phases of this research study.

Data collection and analysis was driven by a clear conceptual framework, incorporating the International Classification of Functioning and Theory of Change. As well as a comprehensive literature review on the epidemiology, classification and impact of hearing loss and a review of hearing aid usage, impact and aural rehabilitation programmes.

This study was based on a relatively large sample size including 184 cases and 143 controls. Such participant volumes provided sufficient power for many of the statistical analyses.

Robust and systematic methodological processes were introduced during the planning and implementation phase of this research project. In-depth data was collected on a multi-dimensional range of facets of life, guided by the Theory of Change conceptual framework, including poverty, quality of life and mental health using standardized validated question sets. The use of qualitative data collection methods, such as the in-depth interviews complemented the quantitative research and improved data interpretation and understanding.

This research project was planned, coordinated and managed by the author, a full-time researcher within the International Centre for Evidence in Disability at the London School of Hygiene & Tropical Medicine.

Acting as Project Manager, the author was based in Guatemala for the duration of the fieldwork and in London for the analysis and report writing process.

The project was supported by a dedicated and experienced Research Supervisor and a highly qualified Advisory Committee which included audiology clinicians, specialist researchers and public health experts. The Advisory Committee provided technical advice and guidance.

Within Guatemala, an effective working relationship with the Sonrisas que Escuchan Foundation and FUNDAL was established. This facilitated case and control management, trouble-shooting and administrative support.

The interviews were conducted in the participant's home, which as compared to a clinical environment, provided a rich and meaningful understanding of the participant's household living conditions and verification of their socio-economic status.

This research project used information technologies to facilitate timely and accurate data collection. This included the use of portable electronic tablets to capture questionnaire responses and for a hearing screening assessment to be conveniently performed in the field. This research study is one of the first projects to examine the quantifiable, data-logging functionality of hearing aids (objective measure of usage) and correlate these with subjective outcome measures of hearing aid usage within a low-middle income setting.

5.8 Research Study Limitations

The section reviews the key challenges and constraints to this research project.

The question sets incorporated within the research questionnaire had been developed and validated on different populations. These represented different geographical locations, cultures, socio-economic positioning, age groups and time frames. The majority were assessed and validated within high income settings such as the USA and Northern Europe. Due to specific question context, meaning and translation their relevance and validity in Guatemala may be challenged. However, this is unlikely to have been an important issue, as most of the tools have been widely used, including in LMICs, and each question set was pilot tested and seemed to be comprehensible to each participant.

Based on pre-determined suitability criteria, each case participant identified a matched control. The control was screened for hearing loss using the portable, Shoe-Box Audiometer prior to being interviewed. This screening process was to ensure that only control participants with normal hearing (as defined by the WHO Classification, above 25dB) were included in the research.

Unexpectedly, hearing loss (classified as mild-severe) was detected in 66% of all control participants. These results excluded their participation in the study and required additional matched subjects to be sourced, identified and tested prior to interview. Such findings impacted on allocated fieldwork time and efficient

resource utilization, for example it took far longer to locate, assess and identify eligible controls. To effectively address these issues and increase the number of eligible control participants in collaboration with key stakeholders, a comprehensive and phased management plan was implemented. (as described in the methods)

Two changes were made to the eligibility protocol, that may have impacted on the results. Firstly, to source, identify and increase the number of eligible control participants without hearing loss, the age range criteria was extended from 5 to 10 years. As a consequence, cases were older than controls, and so the potential for residual confounding after adjustment for age would increase.

Secondly, the eligible threshold for interview and control participation was increased, from normal hearing to permitting the detection of mild hearing loss. (26-40db) However, this meant that cases and controls would be more similar with respect to key outcomes, and so the study may have been under-powered to detect a difference.

The fieldwork was conducted at baseline in October – December 2015 and at follow-up in July – August 2016. There was a variable delay period between case screening and identification and the cases participation in the research study of between one week and up to six months.

The period of time between hearing aid fitting and follow up represented a relatively short time frame, ranging between 6-8 months and a mean period of 7.5 months. Such limited timescales may account for or contribute to no significant change in per capita and household expenditure or asset ownership being identified at follow-up. Other factors that may have made it more difficult to detect an impact on poverty include the age of the participants and their retired work status. 59% of cases were over the age of 60 and the mean age of cases was 61 (Median: 65) as compared with controls at 54. (Median: 57)

Bias can be defined as any systematic error in the design, conduct, or analysis of a study. Bias can arise from two different sources; the approach adopted for selecting subjects for a study (Selection bias) or the approach adopted for collecting or measuring data from a study.[210] (Information bias). There are three specific forms of information bias and these are described below.

Cases were selected to participate in the study based on their inability to afford hearing aids and eligibility for subsidized devices, meaning that they were below a poverty threshold. Cases therefore represented a socio-economically poor population, which would impact on the generalizability of the results. Furthermore, the cases at baseline may have been poorer than the control group in part due to the method of selection of cases. This potential bias may have been partially offset by the selection of the control group from the same community and neighborhood as the cases. Furthermore, this potential selection bias should not have impacted on the change between baseline and follow-up in cases and controls.

The sample was specifically restricted to adults and therefore the results may not be generalizable to children or people not poor, or indeed outside of the geographical area where the study was conducted. There were other factors that may have enhanced the likelihood of selection bias.
Case screening was conducted by the Sonrisas que Escuchan Foundation using clearly defined and specific research eligibility criteria. This process was not part of the research investigation and as such, there was no access to data on case family history, age of onset, specific type and cause of hearing loss as well as markers of health (e.g. pre-existing health conditions) and medication use. As these variables were unknown, I was not able to assess whether there was a difference in impact of hearing aids for different groups (e.g. those with young versus older onset), or to adjust for potential confounding variables (e.g. pre-existing health conditions).

The Sonrisas que Escuchan Foundation's qualified and experienced Audiologist used the results of the assessment, hearing test and otoscopic examination to determine the appropriateness and clinical indication for hearing aid prescription during their community screening programme. Cases that had been assessed and met the research eligibility criteria were identified by the Sonrisas que Escuchan Foundation Executive Director and communicated via e-mail to the Lead Interviewer. Each case was formally identified on a spreadsheet, including their full name, date of birth, contact information (address and telephone number) and their hearing test outcome, displayed as a threshold banding, ranging from

moderate-profound. No numerical hearing test score or case specific assessment data was provided.
It is acknowledged that people with some types and levels of hearing loss, such as an impairment that is classified as profound, may gain limited or no benefit from the use of hearing aids. Such a classification would therefore reflect in lower satisfaction with amplification case scores. However, they were unlikely to have been referred by the Sonrisas que Escuchan Foundation for hearing aids, and so would not have been included in the study.

A proportion of cases (25%) and controls (38%) were lost at follow-up predominantly due to being unable to contact or locate them. It was assumed that these individuals had changed their contact details, geographically moved away or had decided not to participate and respond. The minority of cases and controls that were lost to follow up were not different to those that remained in the study and therefore the chance of selection bias was deemed as small.

This research project aimed to identify 200 cases and 200 controls. This sample size was appropriate at baseline to detect an odds ratio of 1.85, comparing cases and controls for the association between poverty and hearing impairment, assuming that 25% of controls are in the poorest quartile, with 80% power and 95% confidence. In comparison, at follow up to detect a 30% change in quality of life associated with hearing aid use to be detected, with 80% power and 95% confidence. This factored in loss to follow-up and non-compliance with hearing aids, so that 100 cases were available at both time points.
In reality, at baseline there were 180 cases compared with 135 at follow up, representing a 25% reduction. There was also 143 controls at baseline compared with 89 at follow-up, representing a 38% reduction. This reduction in the number of controls may have under-powered the results to detect the anticipated differences between the two groups.
Two-thirds of the cases (66%) were aged 60 years or above, compared with one-third (33%) of the controls. The cases were older than controls and age is likely to be a confounder of the associations between hearing loss and the key outcomes. (e.g. poverty, quality of life, mental health) I was able to adjust for age in the regression models, but there is the potential for some residual confounding

after adjustment for age because of the mis-match between cases and controls. Unfortunately, there is not a statistical test to assess the presence of confounding or residual confounding.

Different types of information bias may have occurred. Self-reporting data can be affected by an external bias caused by social desirability or approval, especially where private or sensitive topics are being discussed such as questions on income, suicide or intimate relationships. In this research study, cultural sensitivity training was provided to the fieldworker team and anonymity and confidentiality was assured at the time of data collection. Despite providing assurances of hearing aid provision and study involvement, this form of bias may have been evident by cases exaggerating or under-reporting their hearing loss and desire or need for intervention. Social desirability factors may have influenced the questionnaire responses and the results of the auditory tests.

Recall Bias may be caused by cases or controls being unable to accurately recall time-specific data. For example, questions relating to expenditure or activity performance from the previous week or month. To minimise the effect of recall bias a short recall period was applied for example, using the day before or previous week. In terms of expenditure data, the lack of difference in expenditure on food compared to other types of expenditure implies that this information was recalled with limited bias.

From an ethical perspective it was not possible to conduct a Randomised Controlled Trial or possible to mask the interviewers or responders to the case/control status, which therefore may generate measurement error and bias. This form of bias is based on the preconceived knowledge and expectations of the researcher. For example, the phrasing of a specific question based on an expected response may distort the outcome of the results. This study minimised the possibility of such bias by developing and following well-designed study protocols, using validated question sets and ensuring robust, competency-based fieldworker training.

A final potential limitation of this study was that the cases had all agreed to accept the hearing aid intervention. It was therefore difficult to explore barriers to and facilitators of uptake of hearing aids using this group. In summary, this section has identified the key forms of bias and described the adjustment methods used to minimise such limitations and maximise the validity of the research findings.

5.9 Further Research

This section of the discussion proposes areas for further research.

5.9.1 Extended Follow-Up

This research study followed up cases and controls after a mean post-intervention period of 7.5 months. An extended case and control follow-up study, performed at two years and five years would enable the longer-term impact of hearing aid use to be assessed.

Based on the Theory of Change, specific long-term impact measures of interest would include case and control comparisons in mental health, employment status, housing conditions, income and expenditure and asset ownership. As an example, a previous impact study aimed to assess the six-year impact of cataract surgery on health-related quality of life, daily activities and economic poverty in Bangladesh and the Philippines.[211] The study found that in the first year, post-surgery there was an impact on expenditure but a significant impact on asset acquisition was not identified until after five years.

5.9.2 Cost-Effectiveness Analysis

Cost-effectiveness analysis is a method for assessing the gains in health, relative to the financial cost of different health interventions.[212]

In the context of this research project, a cost-effectiveness analysis would provide information about the costs of improving the hearing health of the population by means of hearing aids, as well as other interventions such as addressing the root causes of hearing loss in the workplace, aural rehabilitation and surgical intervention. Such information would help to inform policy development, resource utilisation and decision making.

There is currently a lack of research within LMICs comparing patients who pay for their hearing aids or make a subsidized financial contribution to those who receive hearing aids for free. Within the context of the study, methods of means testing and the adoption of different price points could be reviewed and evaluated to determine how they affect accessibility, outcomes and usage.

5.9.3 Randomised Controlled Impact Study

This research project was based on a case-control impact study, however as an alternative, or in comparison, an RCT could be conducted to measure the short-term impact of hearing aids. It would be considered unethical to randomise this study, however by using a waiting list, people are provided with hearing aids after a short waiting period. Such an approach may improve research reliability and enable wider generalisations to be formulated.

5.9.4 Research Generalisation

This research project was limited to an adult population living within a 150 Km radius of Guatemala City. A similar study could be undertaken within other rural or remote areas of Guatemala or extended to other Central American or LMIC's, to determine whether a different geographical location would have the same effect and generalisable outcome.

This research study has focused on the ear and hearing health of an adult population however, in further research it would be useful to examine the impact of hearing impairment and hearing aid provision on activity participation and quality of life in children living in Guatemala. This study would also allow the opportunity to explore the prevalence of hearing loss in children and the impact on early stage communication, social development and learning ability. The concept of inter-generational poverty could also be explored.

5.9.5 Stigma

This research project has identified shame and stigma as an important cross-cutting issue. In the first instance, further research is necessary to understand

the magnitude and nature of stigma and its specific impact, this may be followed by testing strategies for mitigating stigma.

Research on stigma is concerned with distinctly different questions than the epidemiology of the target condition.[204] It is therefore recommended that both quantitative and qualitative assessments are employed to examine the culturally-specific dimensions of stigma. This includes, reluctance to disclose the problem, exclusion or rejection from school, work, social groups and activities, blame, diminished self-esteem, economic measures, ability to marry and social impact and acceptance within the family and wider community.

5.9.6 Hearing Loss Prevalence Study

In many LMIC's, including Guatemala, hearing loss prevalence data is scarce and where it is available, it is often of low quality.[52] This research study performed audiometric screening tests on the control group and identified a substantial number of control subjects with previously undetected and undiagnosed hearing loss. This may suggest that prevalence studies within LMICs, commonly using self-reported measures, may be under-reporting or masking the magnitude of hearing loss.

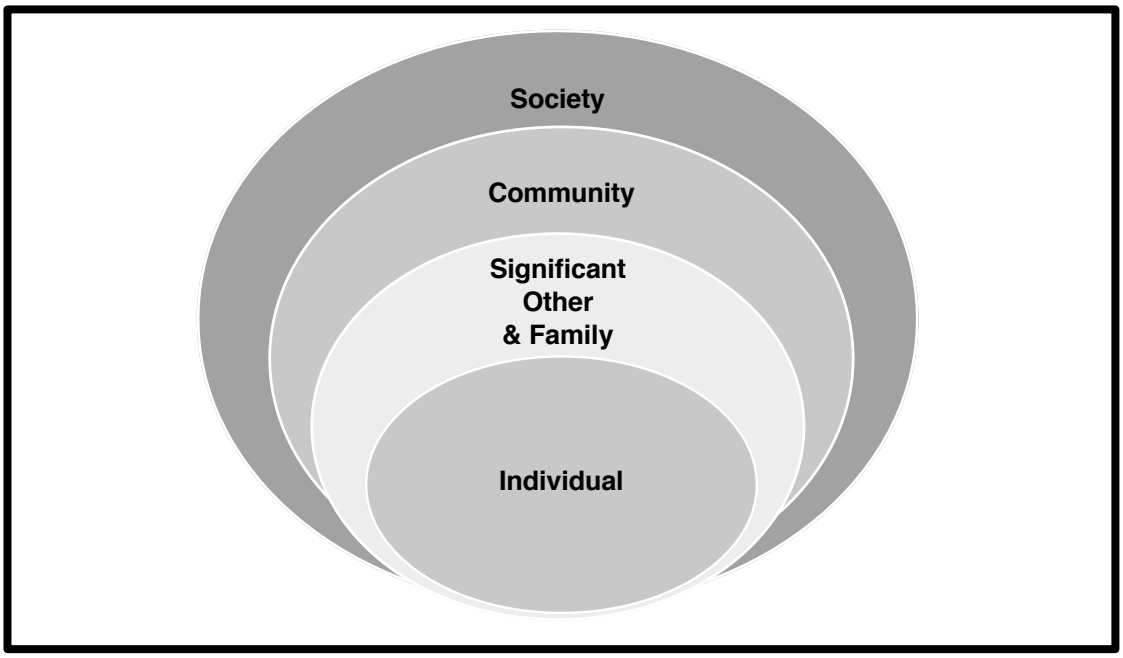
By applying a standardised hearing test using a small, portable electronic tablet, researchers with minimal training may capture quantifiable data in the field, reaching remote areas and communities. Such information would provide reliable statistical data on the national prevalence of hearing loss and enable international comparison and classification. This epidemiological data would provide evidence to support a national screening programme, enable detailed economic analysis and facilitate intervention planning.

5.10 Research Implications & Recommendations

This section discusses the implications of the research project and proposes a set of strategic and operational recommendations for the Ministry of Health in Guatemala. The recommendations are transferable and relevant to other regions and LMIC's. The target population are adults living in rural and urban areas of Guatemala. A systems approach to recommendation planning and implementation is advocated.[217] This conceptual framework (Figure 55) identifies

the individual with hearing loss at the core, with the impact of hearing loss and hearing aid intervention having a significant, multi-directional effect on the family, community and wider society. For recommendations to reach the target population and be effective and sustainable they need to be addressed at all levels.

Figure 55: Systems Framework for Recommendation Planning



5.10.1 Outreach Programme Extension

The positive outcomes and high satisfaction ratings identified in this study were likely to be in part due to case participants being assessed and professionally fitted with quality devices of a basic specification, supplied by a reputable manufacturer. Each case participant was provided with ongoing aftercare and maintenance services. All elements of this aural rehabilitation programme are likely to be important in order to maximize usage and benefit.

Case participants reported that affordability and lack of awareness and knowledge were two of the most important barriers to not having previously obtained help for their hearing loss. These findings have implications for promoting auditory health, for instance in schools and health centres and the

wider community, as well as improving service accessibility and affordability, by extending the community-based aural rehabilitation service model.

The development, scale-up and expansion of existing community based out-reach facilities is needed, potentially to specifically target the most vulnerable, elderly or disabled indigenous adult populations in Guatemala although more data is needed on coverage of hearing aids by different population characteristics before this can be confirmed. Such individuals may be particularly vulnerable as they lack the means to access or are unable to travel to central, urban based healthcare facilities.

Novel options may be developed and tested to improve outreach of hearing services. One option could be to train members of the community as 'Hearing Support Workers'. These individuals would be supported by an experienced and qualified audiology team, to carry out basic hearing aid maintenance and aural rehabilitation services and where appropriate, provide timely and appropriate referral to a clinical audiology specialist.
As an example, a previous randomised controlled trial assessed the feasibility and acceptability of training community health workers (CHWs) in ear and hearing care, and their ability to identify patients with ear and hearing disorders in Malawi.[213] The training was effective in improving the knowledge of community health workers in ear and hearing care in Malawi and enabled them to identify people in the community requiring ENT services. The study concluded that training of CHWs and their identification of patients with ear and hearing disorders could be scaled up in Malawi and tested in other low-income and middle-income countries.

In summary, the extension of community out-reach services, would enable service needs and requirements to be identified and prioritised and socio-economic status and hearing aid affordability to be objectively evaluated. Such locally provided and sustainable services will mitigate the negative impact of hearing loss and positively contribute to improved communication, mental health and quality of life.

5.10.2 Ear & Hearing Health Promotion

Outreach activities would need to be complemented by advocacy and health promotion activities to increase the awareness of hearing loss, its causes, impact and prevention strategies amongst an adult population.

Practical interventions such as, devising and distributing promotional literature, introducing a television, radio and social media campaign, employing community hearing champions to provide training and local service sign-posting. Such events and activities would hope to reduce stigma and discrimination and promote health seeking behaviours. To effectively facilitate this initiative, the WHO has developed and implemented a basic training manual which could be used for interactive and culturally appropriate training for members of the community, such as health workers, teachers and parents.[214] This resource focuses on community involvement and raising awareness as well as covering basic measures for prevention and management.

Case participants reported that affordability of hearing devices was one of the key reasons for not accessing help. Means-tested subsidisation or affordable repayment programmes will promote self-help behaviours and increase accessibility to hearing aids.

5.10.3 Ear & Hearing Health Strategic Planning

There is anecdotal evidence that there is currently a lack of national strategic planning for ear health and hearing in Guatemala and the needs of the target population remain unknown and unmet.

It is thought that current policies and planning documents are inadequate and do not address the funding, resource or logistical requirements that support effective implementation of sustainable ear and hearing care services across the country. As defined by the WHO; a national ear and hearing care strategy should seek to reduce the prevalence, incidence and impact of hearing loss in the community, through public health approaches that are integrated with the country's health system and service delivery.[52] The development of a holistic and integrated strategic plan is the first step towards provision of effective and sustainable ear and hearing care services.

In the first instance, it is recommended that a formal review and assessment of the current strategic position is undertaken. Such a review should be undertaken by a senior committee or task force comprised of ear and hearing health professionals, Ministry of Health representatives and public health experts.
At this time, further research may be necessary to collect and analyse data on the epidemiology of hearing loss in Guatemala and coverage of hearing aids. Such data will provide evidence to support the implementation of these initiatives and form part of the communication plan.
The literature acknowledges that community understanding and social policy relating to ear health and stigma needs to be informed by research, so that laws and health policy are not influenced by stereotypes, prejudices and unfounded speculation that may magnify risk.[204]
The outcome of a cost-benefit analysis may provide incentive, demonstrating that such investment will increase productivity and produce societal cost savings.

The national ear and hearing care plan will also need to address resource provision, assessing the current position and determining future needs. A training needs analysis could be undertaken to identify the national and regional workforce requirements, including volume and skill-mix of ENT & audiology healthcare professionals. This exercise would lead to the formulation of a comprehensive development plan which, based on a clear set of capability-building objectives, would address any human resource and skills gaps and propose a long-term strategic, operational and financial management plan. The future workforce recruitment, education and succession planning requirements would also need to be addressed.

Clinical premises, equipment and transportation are required to provide effective and consistent aural screening, assessment and rehabilitation services. Clinic based services provide a fixed, permanent hub from which mobile services may be deployed. An inventory of clinical premises, furniture and hearing assessment and ear mold production equipment needs to be identified and recorded. Gaps in resource provision may then be determined and a purchasing plan devised. This plan will consider long-term maintenance contracts, servicing

requirements and equipment replacement costs. Competitive financial incentive will be provided through economies of scale and long-term planning.

The collective involvement and commitment of these primary stakeholders as well as the outcome of further research will help support the development and implementation of an adequately funded, sustainable strategic hearing and ear health policy and plan.

5.11 Dissemination of Evidence

The results of this research study and the existing academic body of knowledge demonstrate that hearing loss is related to poverty, reduced quality of life and mental health and that provision of hearing aids may alleviate these negative impacts. In response, it is recommended that a communication plan is devised which identifies the target audiences, the key communication objective and message, mode of delivery and outcome measurement. The outcome of this research should be shared and appropriately communicated to a broad range of stakeholders, including:

5.11.1 National Ministry of Health in Guatemala

To inform policy decision-making and to assist with the formulation of national evidence-based strategies on auditory screening, hearing loss management and rehabilitation.

5.11.2 International Non-Governmental Organisations

To provide evidence that justifies and strengthens the case for supporting and funding aural rehabilitation programmes and hearing aid provision within low and middle-income countries.

5.11.3 International Health Organisations & Research Communities

To build collaborative partnerships which support further research, provide targeted funding and resources and lobby governments. To contribute to the

current work of the WHO assisting with the development of internationally agreed, hearing standards, procedures and rehabilitation protocols.

In summary, this discussion chapter has presented the key findings of the research and the barriers and facilitating factors to intervention. The research outcomes and the proposed Theory of Change have been reviewed in the context of the existing academic body of knowledge. The strengths and limitations of the research methodology as well as areas for further research have been explored. Finally, based on a systems framework, recommendations for strategic planning, resource management and service provision have been proposed.

6. Conclusion

This research study has demonstrated that hearing aids have a positive impact on specific measures of quality of life and mental health among a low-income population of adults with disabling hearing loss living in Guatemala.

Although several multi-dimensional measures of poverty including, employment status, expenditure and asset ownership did not reach a statistically significant difference between cases at baseline and follow-up, there was evidence that hearing aid usage was buffering and protecting the cases from the economic losses experienced among the controls and the decline in living standards occurring in Guatemala. The qualitative analysis helped to provide a detailed interpretation of the quantitative data. A longer follow up period may be required to ascertain a statistically significant impact of hearing aids on reducing poverty. On this basis, the null hypothesis is rejected.

Some of the key barriers and challenges to intervention include lack of ear and hearing health awareness, stigma, financial cost and audiology clinic accessibility. These collective methodologies have provided greater insight and understanding of the impact of hearing loss and the provision of hearing aids within this specific population.

The outcomes of this research have implications for ministerial advocacy, health promotion, aural rehabilitation programme development and community outreach expansion. This study has made a positive contribution to addressing the unmet research needs within a middle-income country such as Guatemala.

7. Personal Reflective Statement

I have a clinical background in Physiotherapy and over twelve years of UK healthcare management experience within the National Health Service (NHS) and private-sector, including strategic and operational roles in workforce planning, clinical education and risk management. Since graduating with a Masters' Degree in Business Administration, I have had a long-term ambition to return to post-graduate education and complete a programme of doctoral research. In 2013, I made the professional and personal decision to undertake a full-time Master of Research Programme at University College London as a prerequisite to doctoral study, with the aim of building my confidence and developing my research capability.

I decided to apply for the Doctor of Public Health Programme (DrPH) at the London School of Hygiene & Tropical Medicine (LSHTM). The structure and content of the DrPH programme appealed to me as, unlike the PhD, it incorporated taught modules, the opportunity for placement within a public health organisation and engagement in multiple research projects. As a physiotherapist, my research interests were in disability and health and a preliminary review of the literature identified a specialist education and research hub within LSHTM, known as the International Centre for Evidence in Disability. (ICED) This provided an opportunity to concentrate my studies on a specific public health domain, the global impact of disability.

During a preliminary interview with the Director of ICED, Professor Hannah Kuper, I was able to identify and discuss my aims and objectives for undertaking the DrPH programme including developing a broader understanding of public health and the multi-dimensional aspects of disability, being able to apply my current knowledge and skill set to real-world health challenges and have the opportunity to plan and implement a research project overseas. Upon acceptance, I started the full-time DrPH Programme in October 2014.

7.1 Taught Modules

My fellow DrPH student cohort were from a broad range of backgrounds, including healthcare, advocacy, management and academia, working within the public, private and charitable/NGO sectors and living in the such locations as the United States, South Africa, Ethiopia and the UK. Such a mature and diverse group made for lively debate, shared experiences and the opportunity for contextual learning.

During the first term of the academic year, two taught modules were undertaken including, 'Evidence Based Public Health Practice' (EBPHP) and 'Understanding Leadership, Management & Organisations' (ULMO).

The Evidence Based Public Health Practice Module focused on how evidence such as academic research and literature is acquired and how it's quality is evaluated. Previously, I have always assumed that because an academic paper is in print and was written by an accomplished author, it is of high quality. Participation in this module and the successful completion of two assignments provided me with a detailed insight and understanding of the dynamic relationship between research, policy and practice in the field of public health. My confidence and ability to question and formally evaluate the content of academic literature continues to develop.

The 'Understanding Leadership, Management & Organisations' taught module was delivered concurrently and provided a critical understanding of different theories concerning the way people work and behave in organisations, including the nature of power and politics and how this effects leadership and managerial decision-making.[215] At first, I found it challenging applying knowledge from my previous business administration studies, which predominantly focused on private sector organisations, to an international public health context. However, although some business models were inappropriate and did not translate into a public health setting, many frameworks could be effectively applied, providing greater context-specific clarity and understanding.

The planning and implementation of the module assignment enabled organisational theories and management tools to be applied. I explored the complex and dynamic internal and external environments in which a UK-based public healthcare service operates.

The three-day residential professional development workshop provided a focused, insightful and 'safe' environment from which to reflect and learn about our leadership styles, personality traits, team building skills and developmental needs. Participation in the self-development exercises acknowledged my social skills and provided insight into building confidence and workplace conflict management. I also identified future career aspirations in leadership, project management and teaching within the domains of disability, risk management and public health intervention.

7.2 Organisational Policy Analysis (OPA)

The purpose of the OPA project was to analyse and evaluate how a public health organisation functions to influence public health policy and/or deliver public health goals.[215] The aim of my OPA was to evaluate how an integrated education and exercise rehabilitation programme for adults living with HIV, based at a large NHS Hospital in London, functions in practice as compared with the intended programme theory.

The intended programme theory was described using a logic model and how the programme operates in practice was determined by capturing the experiences of programme referrers, contributors and participants and identifying the key contextual barriers and facilitating factors to programme implementation. The extent to which the internal, organisational factors and external relationships constrained, or enhanced delivery of the programme were also assessed. To address its core objectives, this research project undertook a structured programme of primary research. This included eighteen qualitative interviews, non-participatory observational analysis and a review of secondary literature and data sources.[216]

The OPA identified a prioritised set of strategic and operational recommendations which were communicated to Hospital Trust Managers through a formal report and via an open presentation and feedback forum involving service-users and internal stakeholders. The recommendations contained within the report were accepted and are currently being implemented.

The most challenging aspects of the OPA was defining its core objectives and ensuring that the project effectively met the academic requirements of the DrPH programme and the expectations of the host organisation. My previous experience of report writing in healthcare management had been in producing broad, action-centred business management reports, whereas the OPA required a formal, academic structure and layout, applying an appropriate conceptual framework to a concentrated subject matter. Each planning and implementation phase of this OPA provided a valuable opportunity for personal reflection, constructive feedback from key stakeholders and transferrable skill development. For example, I was able to develop my knowledge and understanding of qualitative research, ethics and data management by participating in a two-day NVIVO training programme, reviewing recommended literature and obtaining valuable guidance from experienced practitioners.
Collectively, these transferable skills and the completion of the taught modules provided a theoretical grounding and practical foundation for the research project.

7.3 Research Project

The final element of the DrPH programme involved planning and implementing an independent research project and producing a thesis. My initial research plans changed and became more focussed in the first year of the programme when I was presented with the opportunity to manage a project that was of significant personal interest and fulfilled my personal development objectives. I have a bilateral hearing impairment and wear hearing aids, and this exciting research project was based on hearing loss and the multi-dimensional impact of hearing aids on an adult population living in Guatemala.

This research study also provided a unique opportunity for me to conduct research within an international low resource setting and to learn about the culture and communities within a Central American country.

Over the following two years, I was able to make three extended visits to Guatemala. Acting as the Project Manager, I coordinated the Fieldwork team, managed resources, applied problem-solving skills and ensured effective stakeholder communication. I also learnt new, transferable skills such as designing questionnaires and qualitative question sets, delivering a training programme using a language interpreter, managing a project remotely and experience in managing unplanned or unexpected results, for example the high level of hearing loss which was detected amongst the control group, which required the effective planning and implementation of 'Plan B'.
The research project used a mixed methods approach, however, based on my previous experience, I was most comfortable with the qualitative elements of the work. The analysis of quantitative data was the most challenging component of the project and was supported by supervisor-led tutorials, statistical analysis input from a research project committee member and self-directed learning activities.

Over the last three years I have gained extensive teaching and mentoring experience, including seminar and workshop contributions to the Master of Public Health Programme modules in Global Health and Disability and Rehabilitation. In October 2017 I was provided with the opportunity to present my research findings at a Global Ear & Hearing Health Conference in Miami, USA and publish my work within the academic literature.

The Doctor of Public Health Programme has provided a unique opportunity for knowledge and skill acquisition, personal reflection and professional development. Exposure to different organisations and international cultures, as well as the ongoing, constructive feedback from my supervisor, mentors and peers has helped me to develop and gain confidence in my own capabilities and how these can be nurtured and applied. Overall, my participation in the Doctor of Public Health Programme has been a rewarding and challenging experience as well as an intrinsic, personal and professional journey of self-discovery.

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Appendix 1

London School of Hygiene & Tropical Medicine

Ethics Committee Approval

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
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Observational / Interventions Research Ethics Committee

LSHTM

3 June 2015

Dear

Study Title: The impact of hearing impairment and provision of hearing aids on poverty, activity participation and quality of life in Guatemala City

LSHTM Ethics Ref: 9688

Thank you for responding to the Interventions Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Covering Letter	Ethics Application Response Letter	22/05/2015	1.0

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Appendix 2

Local Ethics Approval

ZUGUEME

COMITE ETICA INDEPENDIENTE
3ª CALLE 11-36 ZONA 15, COLONIA TECUN UMAN
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e-mail: comitedeeticazugueme@gmail.com www.zugueme.org
GUATEMALA, GUATEMALA 01015

Certificado de Aprobación

LOS SIGUIENTES FUERON APROBADOS:

Fecha Aprobación: 06 octubre 2015
Aprobación expira: 05 octubre 2016
Protocolo Código ZUGUEME: PROZU436-15
Investigador Código ZUGUEME: INVZU354-15

PROTOCOLO No: -- **Patrocinador: World Wide Hearing Foundation International**

Título: Impacto de la discapacidad auditiva y la provisión de audífonos, en la situación socioeconómica, la participación en actividades, la salud mental y calidad de vida en Guatemala

APROBACIÓN INCLUYE:

- Protocolo Versión en Español
- Formato de Consentimiento Parte I y II
- Formato de Consentimiento para Padres de Participantes de 16 y 17 años, Parte I y II
- Cuestionario Grupo de Casos & Control, Intervención Previa, Versión 8.0
- Cuestionario (Impacto)
- Guía para el seguimiento de adaptación de audífonos.
- Currículo de investigador y subinvestigadores

Investigador Principal	**Dra. Patricia Castellanos de Muñoz**
Lugar de Investigación	**Fundación Sonrisas que Escuchan**
Dirección	**6ª av. 6-63 zona 10, Edificio Sixtino I, Of. 505, Guatemala**

LA APROBACIÓN DE ESTE COMITÉ ESTA SUJETA A QUE DURANTE LA INVESTIGACIÓN SE CUMPLA CON LO SIGUIENTE: (Ver atrás)

ZUGUEME
COMITE ETICA INDEPENDIENTE
GUATEMALA, C. A.

Appendix 3

London School of Hygiene and Tropical Medicine Project Roles

Title	Name	Key Roles & Responsibilities
Thesis Author & Doctor of Public Health Candidate	Mark Spreckley	▪ Research Project Planning & Management ▪ Stakeholder Communication ▪ Methods Tool Design & Development ▪ Thesis & Report Development ▪ Fieldwork Lead & Project Manager (Guatemala) ▪ Qualitative Data Analysis ▪ Descriptive Data Analysis ▪ Conference Presentation ▪ Academic Paper Production & Dissemination
Research Supervisor	Professor Hannah Kuper	▪ Research Project Approval ▪ Project Guidance & Support ▪ Key Stakeholder Communication ▪ Report & Document Editor
Research Advisory Committee	Professor Andrew Smith Dr David Macleod Dr Shaffa Hameed Maria Zuurmond	▪ Professional & Technical Guidance & Support ▪ Project Documentation & Report Review & Feedback ▪ Questionnaire Data Statistical Analysis
Finance & Project Support	Jyoti Shah	▪ Financial & Budget Management ▪ Resource & Logistics Administration ▪ Project Contract Management

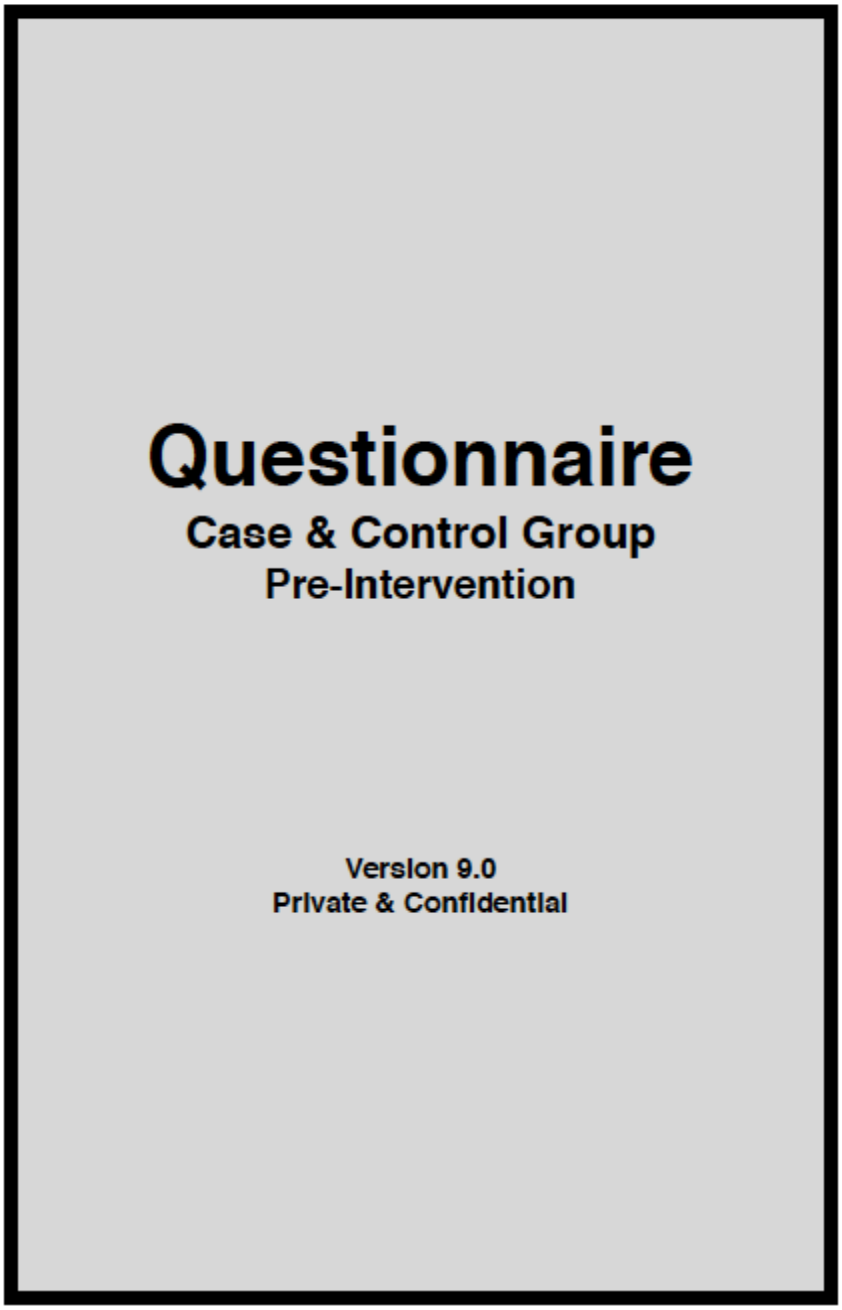
Appendix 4

Project Plan Overview

Year (Quarter)	2015				2016				2017				2018	Outcome
Key Activity	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	
Project Proposal Accepted														Contract & Budget Established
Project Planning & Preparation														Questionnaire Devised Ethics Committee Approval
Guatemala Preliminary Visit														Local Ethics Approval & Research Team Recruited
Baseline Fieldwork														Fieldwork Complete
Post-Intervention Planning														Post Intervention Questionnaire & Schedule Devised
Post-Intervention Fieldwork														Case & Control Survey & In-Depth Interviews Complete
Quantitative Data Analysis														Analysis Complete
World-Wide Hearing Report Writing														Report Submitted
Qualitative Data Analysis Plan														Plan Complete
Doctoral Review: Report & Presentation														Review Complete & Feedback Applied
Qualitative Data Analysis														Analysis Complete
Academic Papers Devised (3)														Finalised, Peer-Reviewed & Publication Process Commenced
Thesis Development														Thesis Submission 2018 (Q1)
Conference Presentation														Presentation Complete

Appendix 5

Pre-Intervention Questionnaire



Content & Navigation

Participants	Parts	Total Number of Questions
Control Group	2-9	102
Case Group	1-11	155

Pre-Interview Information

Ref	Question	Answer ☑	
1	Subject	Case ☐	Control ☐ (Go to Q3)

Ref	Question	Answer ☑		
2	Hearing Impairment	Left Ear ☐	Right Ear ☐	Both Ears ☐

Ref	Question	Answer		
3	Subject Name	First Name	Family Name	Initials (All)

Ref	Question	Answer ☑	
4	Gender	☐ Male	☐ Female

Ref	Question	Answer			
5	Age & Date of Birth	Age (Years)	Day	Month	Year

Ref	Question	Answer			
6	Interview Date & Time	Time: AM/PM	Day	Month	Year

Ref	Question	Answer	
7	Interviewer	First & Family Name Initials	Number

Ref	Question	Answer
8	Interview Address	
9	Geographical Coordinates	

Pre-Interview Checklist	☑
Introductions & Participation Thank You	☐
Research Study Explanation	☐
Information Sheet Read	☐
Consent Form Read & Signed	☐
Question & Answer Opportunity	☐

Part I: Hearing I

Ref	Question	Answer	
1	When did you first realise that you may have a hearing problem? How many months and/or years ago?	☐ Number of Years	☐ Number of Months
2	Apart from now, have you previously tried to seek help for your hearing problem?	Yes ☐ (Go to Q3B)	No ☐ (Go to Q3A)
Ref	**Question**	**Answer**	**☑**
3(A)	If not, what was the **main** reason why you did not seek help before? (Please tick one answer only)	I did not know where to get help	☐
		I could not afford to get help	☐
		I felt embarrassed	☐
		I did not know what help I needed	☐
		I did not need help then	☐
		Other Reason? Specify:	☐
Ref	**Question**	**Answer**	**☑**
3(B)	If yes, what other **main** source of help did you seek? (Please tick one answer only)	Hearing Clinic	☐
		Hospital	☐
		Community Health Service	☐
		Family Member / Friend	☐
		Other Form of Help (Specify)	

Part 2: Household

Ref	Question	Answer ☑	
1	Are you the Head of the Household?	Yes ☐ (Go to Q4)	No ☐

Ref	Question	Answer	
2	Who is the Head of the Household? (Provide Initials)		
3	What is the Head of the Household's relationship to you? ☑	Husband	☐
		Wife	☐
		Father	☐
		Mother	☐
		Grand Parent	☐
		Sibling (Brother/Sister)	☐
		Other (Specify)	☐

Ref	Question	Adults (15 Years +)		Children (Under 15)	
4	Including you, how many household members are there? **Household Member Definition:** Lived in household at least six months of last year, eats meals together, does not pay rent and is not paid domestic help	Total Adults		Total Children	
		Number Male		Number Male	
		Number Female		Number Female	

Ref	Question	Answer ☑			
5	What is your marital status?	Married or Living Together	Divorced /Separated	Widowed	Single
		☐	☐	☐	☐

Ref	Question	Answer ☑		
6	Are you able to read?	☐ Well	☐ Little	☐ Not At All
7	Is the Head of the Household able to read?	☐ Well	☐ Little	☐ Not At All

Ref	Question	Answer ☑				
8	What is the highest level of education you have completed?	No Education	Primary	Secondary/ High School	University	Currently Studying (Also Tick Level)
		☐ To Q 9 & 10	☐	☐	☐	☐
9	What is the highest level of education that the Head of the Household has completed?	☐ To: Part 3	☐ To: Part 3	☐ To: Part 3	☐ To: Part 3	☐ To: Part 3

Ref	Question	Answer	Response ☑
10	What is the **main** reason why you did not receive formal education?	Absence of School	☐
		Lack of Money	☐
		Needed to Work	☐
		Education Not Very Useful	☐
		Don't Like School	☐
		Family Did Not Allow	☐
		No Transport	☐
		My Hearing Problem	☐
		Other: Please Specify	☐

Part 3: Home
(A) Interviewer To Observe & Code:

Ref	Question	Answer	☑
I	**Floor** The **main** material for the floor is:	Cement	☐
		Wood/Planks	☐
		Parquet or Polished Wood	☐
		Vinyl or Asphalt Strips	☐
		Ceramic Tiles	☐
		Earth/Sand	☐
		Carpet	☐
		Other: Specify	☐

Ref	Question	Answer	☑
II	**Roof** The **main** material for the roof is:	Metal	☐
		Wood	☐
		Cement	☐
		Tiles	☐
		Thatch/Palm Leaf/Grass	☐
		Cardboard	☐
		No Roof	☐
		Other (Please Specify)	☐

Ref	Question	Answer	Response ☑
III	**Walls** The **main** material for the exterior walls is:	Brick	☐
		Stone	☐
		Cement Blocks	☐
		Wood	☐
		Bamboo/Cane/Palm/ Trunk	☐
		Cardboard	☐
		No Walls	☐
		Other (Specify)	☐

(B) Home

Ref	Question	Answer	Response ☑
1	Do you or a household member own the home?	Owns	☐
		Rents	☐
		Uses without Paying Rent	☐
		Temporary Dwelling (Nomadic)	☐

Ref	Question	Answer
2	Including all outbuildings, how many internal rooms does your home have? Count all rooms including kitchen, toilet or bathroom but exclude any specific animal accommodation, such as stables	Number of Rooms ☐
3	How many rooms in this household are used for sleeping?	Number of Rooms ☐

Ref	Question	Answer	☑
4	What kind of toilet facility do the members of your household usually use?	Flush to piped sewer system	☐
		Flush to septic tank	☐
		Flush to pit (latrine)	☐
		Flush to unknown place/not sure/don't know where	☐
		Pit Latrine	☐
		Bucket	☐
		No toilet: use bush/field	☐
		Other (Specify)	☐

Ref	Question	Answer ☑	
5	Do you share this toilet facility with other households?	Yes ☐	No ☐

Ref	Question	Answer	☑
6	What type of fuel does your household mainly use for cooking?	Electricity	☐
		Liquid Propane Gas (LPG) Bottle	☐
		Piped Gas	☐
		Coal/Charcoal	☐
		Wood	☐
		Straw/Shrubs/Grass	☐
		Do not cook food at home	☐
		Other (Specify)	☐

Ref	Question	Answer	☑
7	What is the **main** source of drinking water for the household members?	Piped into home	☐
		Piped into yard or plot	☐
		Public tap/standpipe	☐
		Borehole (Hand Pump)	☐
		Well	☐
		Water from Spring	☐
		Surface Water (From River, Stream, Lake)	☐
		Bottled Water	☐
		Other (Specify)	☐

Ref	Question	Answer	☑
8	How do you dispose of your household waste?	Composting	☐
		Recycling some items	☐
		Burning	☐
		Municipal Garbage pick-up	☐
		Dump in forest/open land/river/stream	☐
		Other (Specify)	☐

Ref	Question	Answer ☑	
9	Does any member fo this household own any land?	Yes ☐	No ☐ (Go to Q12)

10	If yes, how much land do they own?	☐ M2

Ref	Question	Answer	☑
11	What do they use this land for?	Crop Farming	☐
		Grazing Animals	☐
		Building	☐
		Rent To Others	☐
		Other (Specify)	☐

Ref	Question	Answer ☑	
12	Does any member of the household own any livestock? For example: Herds of cattle, sheep, horses, oxen or chickens Excluding pets.	Yes ☐	No ☐ (Go to Q14)

Ref	Question	Answer			
		Livestock	No ☑	Yes ☑	Number
13	If yes, what type of livestock and how many?	Horses/Pony			
		Cows / Bull			
		Sheep			
		Pigs			
		Goats			
		Donkey			
		Chickens			
		Other (Specify)			
		Total			

Ref	Question	Answer ☑	
14	Does your household have access to electricity?	Yes ☐	No ☐ (Go to Q16)

Ref	Question	Answer	☑
15	How does your household access electricity?	Legal Connection	☐
		Informal Connection	☐
		Self-Generated Connection (Fuel Generator	☐
		Don't Know	☐

Number	Question	Answer	Response	
16	Does your household have any of the following items that are in working order?		Yes ☑	No ☑
		Radio	☐	☐
		Refrigerator	☐	☐
		Television	☐	☐
		Landline Telephone	☐	☐
		Mobile Phone	☐	☐
		Mattress or Bed	☐	☐
		Computer/Laptop/ Electronic Tablet	☐	☐
		Washing Machine	☐	☐
		Watch or Clock	☐	☐
		Bicycle	☐	☐
		Motorcycle or Motor scooter	☐	☐
		Non-motorised Cart	☐	☐
		Car or Truck	☐	☐
		Boat With Motor	☐	☐

Ref	Question	Answer	
17	Including you, how many household members contribute to the household income?	☐	
18	Does any member of this household hold a bank account? ☑	Yes ☐	No ☐

Part 4: Activity & Work Participation

Ref	What activities do you perform and how frequently?	Did you spend any time in the last **week** performing?		Did you spend any time **yesterday** performing?		How many hours did you spend on these activities **yesterday**?
	Activity	**No** ☑	**Yes** ☑	**No** ☑	**Yes** ☑	**Minutes & Hours**
1	**Household Tasks** For Example: On behalf of you and other household members, looking after others/cooking, washing dishes, cleaning, shopping, traveling	☐	☐	☐	☐	
2	**Paid or Self Employment** For Example: Making & selling products from home/working for a business	☐	☐	☐	☐	Include Transport Time
3	**Household Work** Any work for your own or household use and benefit? Including farming fetching firewood, processing own agricultural products, childcare	☐	☐	☐	☐	
4	**Social Visits** (Ceremonies, Celebrations, Meetings, Church, Visiting Friends & Family	☐	☐	☐	☐	
5	**Leisure Activities** Including reading, listening to the radio, watching TV, entertaining, hobbies and interests	☐	☐	☐	☐	
6	**Daytime Sleeping**	☐	☐	☐	☐	
7	**Other Activity:** Specify:	☐	☐	☐	☐	

Ref	Question	Answer	☑
8	Did you do any type of work in the last 4 weeks that contributes to the household income?	☐ Yes (Go to Q11)	☐ No
9	Have you been looking for work and ready for work in the last 4 weeks?	☐ Yes (Go to Q11)	☐ No
Ref	**Question**	**Answer**	**☑**
10	What was the main reason for not working or looking for work in the last 4 weeks?	Household & Family / Child Care Role	☐
		Seasonal Inactivity	☐
		Student	☐
		No Work Available	☐
		Too Old / Young	☐
		My Hearing Problem	☐
		Other	☐
11	How many jobs did you have in the last year?		Number ☐ If 0: Skip To Part 5
12	Please name the three main jobs in order of importance (Greatest income source first)	Over the last 12 months, how many months did you work on this job?	How many hours per week did you work in the last month?
	Job 1 Title:	☐	☐
	Job 2 Title:	☐	☐
	Job 3 Title:	☐	☐

Ref	Question	Answer	☑
13	Did you work relatively more or less than usual in the last month?	More than usual	☐
		Same as usual	☐
		Less than usual	☐
14	How were you paid for the main job? (Job 1)	Wages/Salary	☐
		Payment in Kind	☐
		Casual (hourly/daily)	☐
		Unpaid or Volunteer	☐
		Self-employed	☐
15	For whom did you work for in your main job?	Government	☐
		Non-Government Organisation	☐
		Private Business	☐
		Private Person/Household	☐
		Other (Specify)	☐
16	What is the **main activity** at the place of your main job?	Agriculture/Farming	☐
		Manufacturing/ Processing	☐
		Building & Construction	☐
		Transport	☐
		Shop/Selling/Vendor	☐
		Hospitality (Waiter/Chef/Housekeeper)	☐
		Education/Health	☐
		Other (Specify)	☐

Ref	Question	Answer	No ☑	Yes ☑
17	Are you entitled to any of the following?	Paid Sick Leave	☐	☐
		Paid Holiday	☐	☐
		Maternity/Paternity Leave	☐	☐
		Retirement Pension	☐	☐
		Social Security Benefits	☐	☐
		Health Insurance/ Free Medical Care	☐	☐

Part 5: Income

Ref	Statement	Answer ☑	
1	I'm now going to ask you some questions regarding you and your household's financial income.	☐ Yes: Proceed To Part 5 Q2	☐ Refused Go to Part 6

Ref	Question	Weekly Amount (Q)	Monthly Amount (Q)
2	What is your weekly / monthly income from your job?		
3	What is the total weekly/monthly income from other household members jobs?		
4	Does the household have any other sources of income? If so, how much? For Example: Do You/Your Household: ▪ Sell products, wash clothes or make food for others? ▪ Have a pension? ▪ Have financial support from your family ▪ Receive any remittances? ▪ Receive any interest on savings or on loans you have made?		
	Total Income Per Week / Month		
	Calculation	**X52**	**X12**
	Total Annual Household Income		

Part 6: Household Spending & Consumption

1. In the past 7 days, has any member of your household spent money on any of the following items?			How much did your household spend on each item?
Items	No ☑	Yes ☑	QUETZAL Q.
Tobacco, cigarettes, cigars	☐	☐	
Newspapers or magazines	☐	☐	
Lottery tickets	☐	☐	
Fares for public transport: busses, taxis, etc.	☐	☐	
Petrol, oil and car service	☐	☐	
Parking	☐	☐	
Charity	☐	☐	
Restaurant or Café Meals, Beverages & Snacks	☐	☐	
Total: Week			

2. Over the past week has your household eaten the following food items?	Eaten		Value	Purchased	Gift	Payment
	Yes ☑	No ☑	Q.	☑	☑	☑
Vegetable Oils & Cooking Fat	☐	☐		☐	☐	☐
Butter or Margarine	☐	☐		☐	☐	☐
Milk Fresh/Sterilised/UHT/Powder	☐	☐		☐	☐	☐
Eggs	☐	☐		☐	☐	☐
Other Dairy Products Example: Yoghurt & Cheese	☐	☐		☐	☐	☐
Vegetables Example: Potato/Salad/Avocado	☐	☐		☐	☐	☐
Fresh Meat & Poultry	☐	☐		☐	☐	☐
Fresh Fish	☐	☐		☐	☐	☐
Fruit: Water Melon/Papaya	☐	☐		☐	☐	☐
Beans	☐	☐		☐	☐	☐
Rice	☐	☐		☐	☐	☐
Nuts	☐	☐		☐	☐	☐
Tortilla	☐	☐		☐	☐	☐
Weekly Total						

3. Over the **past month** has your **household** eaten the following Food Items?	Eaten		Value	Purchased	Gift	Payment
	Yes ☑	No ☑	Q.	☑	☑	☑
Breakfast Cereal	☐	☐		☐	☐	☐
Flour / Grain	☐	☐		☐	☐	☐
Sugar	☐	☐		☐	☐	☐
Baby Formula	☐	☐		☐	☐	☐
Chocolate	☐	☐		☐	☐	☐
Canned Foods (fish, fruit)	☐	☐		☐	☐	☐
Soft Drinks	☐	☐		☐	☐	☐
Beer and Alcoholic Beverages	☐	☐		☐	☐	☐
Biscuits and Cakes	☐	☐		☐	☐	☐
Spices and Condiments	☐	☐		☐	☐	☐
Jam	☐	☐		☐	☐	☐
Tea	☐	☐		☐	☐	☐
Coffee	☐	☐		☐	☐	☐
Any Other Food Items Not Listed Specify:	☐	☐		☐	☐	☐
Monthly Total						

4. Over the **past month** has your **household** spent money on any of the following items?	Spent		Value
	Yes ☑	No ☑	Q.
Personal care items (haircuts, cosmetics, shampoo, toothpaste)	☐	☐	
Clothing or shoes for adults	☐	☐	
Clothing or shoes for children (including school uniform)	☐	☐	
Material to make clothing, curtains and other items	☐	☐	
Telephone (service + calls + prepaid) including Cell Phone	☐	☐	
Holidays & Excursions	☐	☐	
Jewellery, watches and other luxury goods	☐	☐	
Birthdays & Ceremonies (Weddings & Funerals)	☐	☐	
Membership Fees	☐	☐	
Monthly Total			

5. **Entertainment**: Over the **past month** has your **household** spent money on any of the following items?	**Spent**		**Value**
	Yes ☑	**No ☑**	**Q.**
Books & Stationary (Excluding Textbooks)	☐	☐	
Postal Expenses	☐	☐	
Entertainment/Leisure (Cinema, DVD Rentals, Music, Sporting Events)	☐	☐	
Internet & TV / Cable	☐	☐	
Sports / Hobby Equipment	☐	☐	
Total			

6. **Healthcare Expenses**: Over the **past month** has your **household** spent money on any of the following?	**Spent**		**Value**
	Yes ☑	**No ☑**	**Q.**
Medical Insurance Fees	☐	☐	
Hospital/Clinic Costs: Dentists/Doctor/Nurse Fees	☐	☐	
Medical Supplies: Medicines, Bandages	☐	☐	
Natural / Complementary Therapy	☐	☐	
Total			

7. **Household Expenses**: Over the **past month** has your **household** spent money on any of the following?	**Spent**		**Value**
	Yes ☑	**No ☑**	**Q.**
Household Cleaning (soap, washing powder)	☐	☐	
Kitchen Equipment (pots, pans, lamps, torches)	☐	☐	
Bedding Sheets, Blankets and Towels	☐	☐	
Furniture and Household Appliances	☐	☐	
Home Maintenance and Repairs	☐	☐	
Fuel (Firewood, Charcoal, Cooking Gas)	☐	☐	
All Other Household Expenses Specify:	☐	☐	
Total			

8. Education Fees: Over the past month has your household spent money on the following?	Spent		Value
	Yes ☑	No ☑	Q.
School Fees and Tuition	☐	☐	
University Fees	☐	☐	
Other School Expenses (books, transport, meals at school)	☐	☐	
Total			

9. Tax & Legal Fees: Over the past month has your household spent money on any of the following? (Prompt: An annual 1/12th Proportion)	Spent		Value
	Yes ☑	No ☑	Q.
Income Tax	☐	☐	
Land Tax/Land Rates	☐	☐	
Housing and property tax	☐	☐	
Legal or notary services	☐	☐	
Total			

10. Insurance & Fees: Over the past month has your household spent money on any of the following?	Spent		Value
	Yes ☑	No ☑	Q.
Insurance (Car & Property)	☐	☐	
Total			

11. Other Expenses: Over the past month has your household spent money on any other items or services? Please specify below.	Spent		Value
	Yes ☑	No ☑	Q.
Specify:	☐	☐	
Specify:	☐	☐	
Total			

Total Monthly Expenditure (Q)	

Part 7: General Health (Show Card: Scale A)

Ref	Question	No ☑	Yes: Some Difficulty ☑	Yes: Lots of Difficulty ☑	Cannot Do At All ☑
1	Do you have difficulty seeing, even if wearing Glasses?	☐	☐	☐	☐
2	Do you have difficulty hearing, even if using a hearing aid?	☐	☐	☐	☐
3	Do you have difficulty walking or climbing steps?	☐	☐	☐	☐
4	Do you have difficulty remembering or concentrating?	☐	☐	☐	☐
5	Do you have difficulty (with self care such as) with washing all over or dressing?	☐	☐	☐	☐
6	Using your usual (customary) language, do you have difficulty communicating, for example, understanding or being understood?	☐	☐	☐	☐

Part 8: Mental Health (Show Card: Scale B)

Ref	Read Question: Over the last two weeks, how often have you been bothered by any of the following problems?	Not at all ☑	Several Days ☑	More than half the days ☑	Nearly every day ☑
1	Little interest or pleasure in doing things	☐	☐	☐	☐
2	Feeling down, depressed or hopeless	☐ Go To Part 9	☐	☐	☐
3	Trouble falling or staying asleep, or sleeping too much	☐	☐	☐	☐
4	Feeling tired or having little energy	☐	☐	☐	☐
5	Poor appetite or overeating	☐	☐	☐	☐
6	Feeling bad about yourself…or that you are a failure or have let yourself or family down?	☐	☐	☐	☐
7	Trouble concentrating on things, such as reading the newspaper or watching television?	☐	☐	☐	☐
8	Moving or speaking so slowly that other people could have noticed. Or the opposite, being so fidgety or restless that you have been moving around a lot more than usual?	☐	☐	☐	☐
9	Thoughts that you would be better off dead, or of hurting yourself	☐	☐	☐	☐
Ref	**Question**	**Not difficult at all ☑**	**Somewhat difficult ☑**	**Very difficult ☑**	**Extremely difficult ☑**
10	If you have experienced any of these problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	☐	☐	☐	☐

Part 9: Quality of Life (Show Card: Scales C-G)

Ref	Question	Very Poor ☑	Poor ☑	Neither Poor nor Good ☑	Good ☑	Very Good ☑
1	How would you rate your quality of life?	☐	☐	☐	☐	☐

Ref	Question	Very Dissatisfied ☑	Dissatisfied ☑	Neither satisfied nor Dissatisfied ☑	Satisfied ☑	Very Satisfied ☑
2	How satisfied are you with your health?	☐	☐	☐	☐	☐

Ref	The following questions ask about how much you have experienced certain things over the last four weeks?	Not at all ☑	A Little ☑	A Moderate Amount ☑	Very Much or Mostly ☑	An Extreme Amount /Completely ☑
3	To what extent do you feel that physical pain prevents you from doing what you need to do?	☐	☐	☐	☐	☐
4	How much do you need any medical treatment to function in your daily life?	☐	☐	☐	☐	☐
5	How much do you enjoy life?	☐	☐	☐	☐	☐
6	To what extent do you feel your life to be meaningful?	☐	☐	☐	☐	☐
7	How well are you able to concentrate?	☐	☐	☐	☐	☐
8	How safe do you feel in your daily life?	☐	☐	☐	☐	☐
9	How healthy is your physical environment?	☐	☐	☐	☐	☐
10	Do you have enough energy for everyday life?	☐	☐	☐	☐	☐
11	Are you able to accept your bodily appearance?	☐	☐	☐	☐	☐
12	Have you enough money to meet your needs?	☐	☐	☐	☐	☐

13	How available to you is the information that you need in your day-to-day life?	☐	☐	☐	☐	☐
14	To what extent do you have the opportunity for leisure activities?	☐	☐	☐	☐	☐
Ref	Question	Very Poor ☑	Poor ☑	Neither Poor nor Good ☑	Good ☑	Very Good ☑
15	How well are you able to physically move and get around?	☐	☐	☐	☐	☐
Ref	Question	Very Dissatisfied ☑	Dissatisfied ☑	Neither Satisfied nor Dissatisfied ☑	Satisfied ☑	Very Satisfied ☑
16	How satisfied are you with your sleep?	☐	☐	☐	☐	☐
17	How satisfied are you with your ability to perform your daily living activities?	☐	☐	☐	☐	☐
18	How satisfied are you with your capacity to work?	☐	☐	☐	☐	☐
19	How satisfied are you with yourself?	☐	☐	☐	☐	☐
20	How satisfied are you with your personal relationships?	☐	☐	☐	☐	☐
21	How satisfied are you with your close (intimate) relationships?	☐	☐	☐	☐	☐
22	How satisfied are you with the support you get from your friends?	☐	☐	☐	☐	☐
23	How satisfied are you with the conditions of your living place?	☐	☐	☐	☐	☐
24	How satisfied are you with your access to health services?	☐	☐	☐	☐	☐
25	How satisfied are you with transport?	☐	☐	☐	☐	☐
Ref	The following question refers to how often you have felt or experienced certain things in the last four weeks.	Never ☑	Seldom ☑	Quite Often ☑	Very Often ☑	Always ☑
26	How often do you have negative feelings such as blue moods, despair, anxiety or depression?	☐	☐	☐	☐	☐

Part 10: Hearing

Ref	Question	Yes ☑	Sometimes ☑	No ☑
1	Does a hearing problem cause you to use the phone less often than you would like?	☐	☐	☐
2	Does a hearing problem cause you to feel embarrassed when meeting new people?	☐	☐	☐
3	Does a hearing problem cause you to avoid groups of people?	☐	☐	☐
4	Does a hearing problem make you irritable?	☐	☐	☐
5	Does a hearing problem cause you to feel frustrated when talking to members of your family?	☐	☐	☐
6	Does a hearing problem cause you difficulty when attending a party?	☐	☐	☐
7	Does a hearing problem cause you difficulty hearing/understanding co-workers, clients, or customers?	☐	☐	☐
8	Do you feel handicapped by a hearing problem?	☐	☐	☐
9	Does a hearing problem cause you difficulty when visiting friends, relatives, or neighbours?	☐	☐	☐
10	Does a hearing problem cause you to feel frustrated when talking to co-workers, clients, or customers?	☐	☐	☐
11	Does a hearing problem cause you difficulty in the movies or theatre?	☐	☐	☐
12	Does a hearing problem cause you to be nervous?	☐	☐	☐
13	Does a hearing problem cause you to visit friends, relatives, or neighbours less often than you would like?	☐	☐	☐
14	Does a hearing problem cause you to have arguments with family members?	☐	☐	☐
15	Does a hearing problem cause you difficulty when listening to TV or radio?	☐	☐	☐
16	Does a hearing problem cause you to go shopping less often than you would like?	☐	☐	☐
17	Does any problem or difficulty with your hearing upset you at all?	☐	☐	☐
18	Does a hearing problem cause you to want to be by yourself?	☐	☐	☐
19	Does a hearing problem cause you to talk to family members less often than you would like?	☐	☐	☐
20	Do you feel that any difficulty with your hearing limits or hampers your personal or social life?	☐	☐	☐
21	Does a hearing problem cause you difficulty when sitting at a table and eating a meal with relatives or friends?	☐	☐	☐

Ref	Question	Yes ☑	Sometimes ☑	Never ☑
22	Does a hearing problem cause you to feel depressed?	☐	☐	☐
23	Does a hearing problem cause you to listen to TV or the radio less often than you would like?	☐	☐	☐
24	Does a hearing problem cause you to feel uncomfortable when talking to friends?	☐	☐	☐
25	Does a hearing problem cause you to feel left out when you are with a group of people?	☐	☐	☐
	Total			

Ref	Question Scale: 1= Never 5 = Sometimes 10 = Always (Show Scale G)	1-10 Response
26	Do you experience communication difficulties in situations, which involve speaking with one other person? For example: Home/Work/Social Situation	
27	Do you experience communication difficulties when watching television or listening to the radio?	
28	Do you experience communication difficulties in situations when conversing with a small group of several persons? For example: With friends or family, co-workers or over dinner	
29	Do you experience communication difficulties when you are in an unfavorable listening environment, such as at a noisy party, when there is background music, when riding on the bus or when someone whispers/talks from across the room?	
30	How often do you experience communication difficulties in a situation when you need or want to hear well? For example: Trying to hear instructions or information	
31	Do you feel that any difficulty with hearing negatively affects or hampers your personal or social life?	
32	Does any problem or difficulty with hearing worry, annoy or upset you?	
33	Do your family, friends or co-workers seem to be concerned, annoyed or suggest that you have a hearing problem?	
34	How often does hearing loss negatively affect your enjoyment of life?	
35	How often has your hearing problem potentially caused or contributed to a safety or security concern? For example: At home or at work. Please explain what happened?	
	Total Score	

Ref Number	Question	Answer
36	Today, as you are, what would you like to do? What are your current dreams and aspirations?	

Ref Number	Question	Answer
37	Thank you for your help in answering these questions today. Do you have any final comments you wish to share?	

Ref Number	Question	Answer ☑		
38	With your consent, I would now like to ask another member of your household a few questions about your hearing.	Consent Yes ☐ Q39 + Part 11	Unavailable ☐ End Interview	Refused ☐ End Interview

Ref Number	Question	Answer ☑	
39	What is this member's relationship to you?	Husband	☐
		Wife	☐
		Daughter	☐
		Son	☐
		Other: Specify	☐

Interviewer Notes & Extended Answers

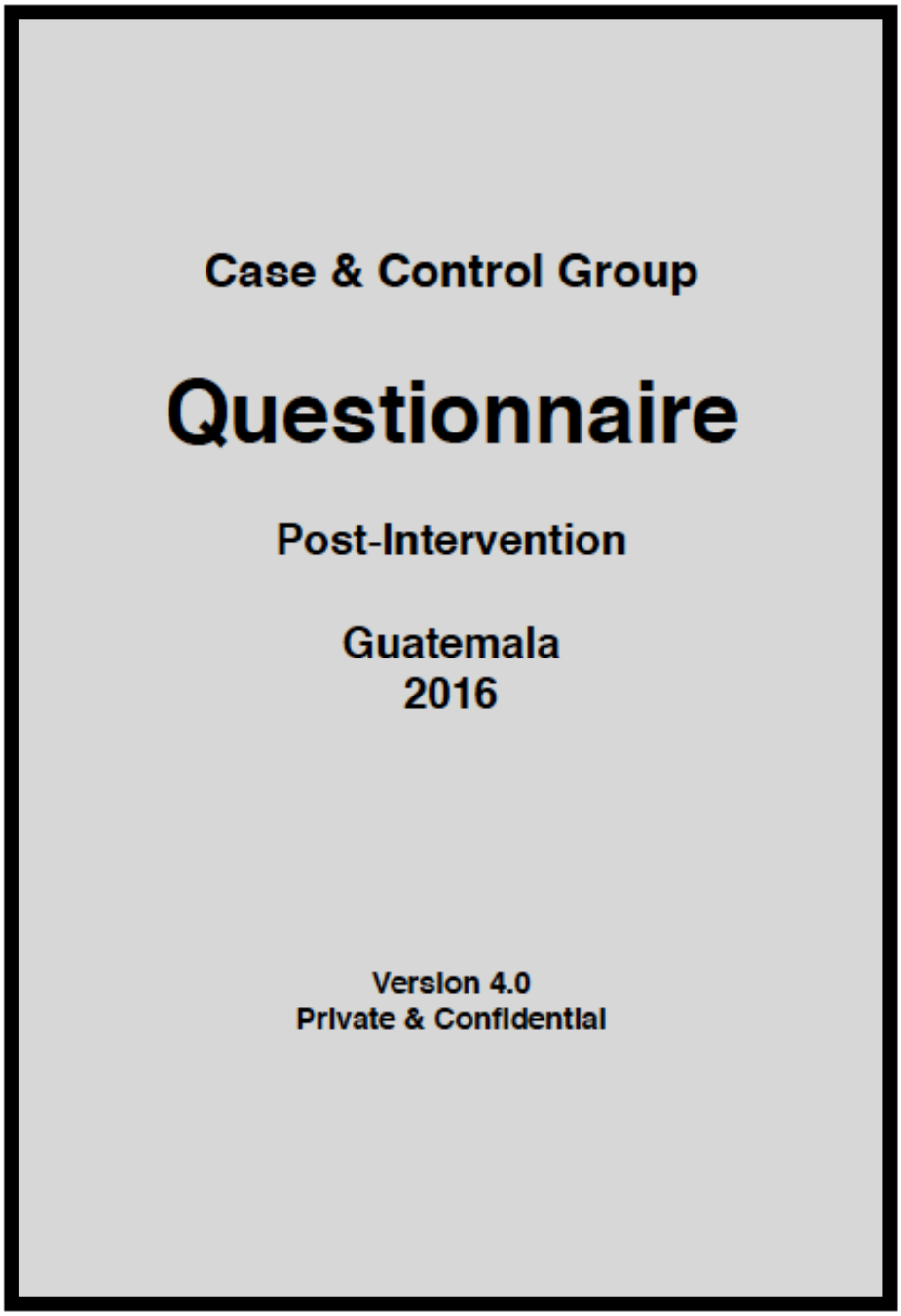
End of Interview

Part 11: Significant Other Question Set

Ref Number	Question 1 = Never 5 = Sometimes 10 = Always (Show Scale G)	1-10 Response
1	Does he/she experience communication difficulties in situations, which involve speaking with one other person? For example: At home, in work or during a social situation?	
2	Does he/she experience communication difficulties when watching television or listening to the radio?	
3	Does he/she experience communication difficulties in situations when conversing with a small group of several persons? For example: With friends or family, co-workers or over dinner	
4	Does he/she experience communication difficulties when they are in an unfavorable listening environment, such as at a noisy party, when there is background music, when riding on the bus or when someone whispers/talks from across the room?	
5	How often does he/she experience communication difficulties in a situation when they need or want to hear well? For example: Unable to hear instructions or information being provided	
6	Do you feel that any difficulty with hearing negatively affects or hampers his or her personal or social life?	
7	Do you feel that any problem of difficulty with hearing worries, annoys or upsets him/her?	
8	Do you or others seem to be concerned, annoyed or suggest that he/she has a hearing problem?	
9	How often does hearing loss negatively affect his/her enjoyment of life?	
10	How often has his/her hearing problem potentially caused or contributed to a safety or security concern? For example: At home or at work. Please explain what happened? (Write notes below)	
	Total Score	

Appendix 6

Post-Intervention Questionnaire



Content & Navigation

Participants	Section: Parts	Total Number of Questions
Control Group	01-08	89
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Pre-Interview Checklist	☑
Introductions	☐
Thank You for Participating	☐
Research Study Explanation	☐
Read Information Sheet	☐
Read Consent Form & Sign	☐
Question & Answer Opportunity	☐

Part 01: Participant Information

Ref	Question	Answer ☑	
1	Subject	Case ☐	Control ☐

Ref	Question	Answer		
2	Subject Name	First Name	Family Name	Initials (All)

Ref	Question	Answer ☑	
3	Gender	☐ Male	☐ Female

Ref	Question	Answer			
4	Age & Date of Birth	Age (Years)	Day	Month	Year

Ref	Question			
5	Post Intervention Interview Date	Day	Month	Year

Ref	Question	Answer	
6	Interviewer	First & Family Name	Team Number

Ref	Question	Answer
7	Interview Address	
8	Geographical Coordinates	

Case Specific Information

Ref	Question	Answer ☑		
9	Hearing Impairment	Left Ear ☐	Right Ear ☐	Both Ears ☐

Ref	Question	Answer ☑		
10	Hearing Aids Fitted	Left Ear ☐	Right Ear ☐	Both Ears ☐

Ref	Question	Answer		
11	Date of Hearing Aid Fitting	Day:	Month:	Year:

Ref	Question	Answer
12	Total number of complete months in possession of hearing aids	☐ Complete Months

Part 02: Household

Ref	Question	Answer ☑			
1	What is your marital status?	Married or Living Together ☐	Divorced /Separated ☐	Widowed ☐	Single ☐

Ref	Question	Answer	
2	**Including you**, how many household members are there? **Household Member Definition**: Lived in household for at least six months of last year, eat meals together, do not pay rent and are not paid domestic help	☐ Adults (15 years+)	☐ Children (Under 15)

Ref	Question	Answer
3	**Including you**, how many household members contribute to the household income?	☐

Ref	Question	Answer ☑	
4	Does any member of this household own any land?	Yes ☐	No ☐ (Go to Q6)
5	If yes, how much land do they own?	☐ M²	

Ref	Question	Answer ☑	
6	Does any member of the household own any livestock? For example: Herds of cattle, sheep, horses, oxen or chickens. Excluding pets.	Yes ☐	No ☐

Ref	Question	Answer	Response	
7	Does your household have any of the following items that are in working order?		Yes ☑	No ☑
		Radio	☐	☐
		Refrigerator	☐	☐
		Television	☐	☐
		Landline Telephone	☐	☐
		Mobile Phone	☐	☐
		Mattress or Bed	☐	☐
		Computer/Laptop/Electronic Tablet	☐	☐
		Washing Machine	☐	☐
		Watch or Clock	☐	☐
		Bicycle	☐	☐
		Motorcycle or Motor-Scooter	☐	☐
		Non-Motorised Cart	☐	☐
		Car or Truck	☐	☐
		Boat With Motor	☐	☐

Part 03: Activity & Work Participation

Ref	What activities do you perform and how frequently?	Did you spend any time in the last **week** performing?		Did you spend any time **yesterday** performing?		How many hours did you spend on these activities **yesterday**?
	Activity	**No**	**Yes**	**No**	**Yes**	**Minutes & Hours**
1	**Household Tasks** For Example: On behalf of you and other household members, looking after others/cooking, washing dishes, cleaning, shopping, traveling	☐	☐	☐	☐	
2	**Paid or Self Employment** For Example: Making & selling products from home/working for a business	☐	☐	☐	☐	Include Transport Time
3	**Household Work** Any work for your own or household use and benefit? Including farming fetching firewood, processing own agricultural products, childcare	☐	☐	☐	☐	
4	**Social Visits** (Ceremonies, Celebrations, Meetings, Church, Visiting Friends & Family	☐	☐	☐	☐	
5	**Leisure Activities** Including reading, listening to the radio, watching TV, entertaining, hobbies and interests	☐	☐	☐	☐	
6	**Daytime Sleeping**	☐	☐	☐	☐	
7	**Other Activity**: Specify:	☐	☐	☐	☐	

Ref	Question	Answer	☑
8	Did you do any type of work in the last 4 weeks that contributes to the household income?	☐ Yes (Go to Q11)	☐ No
9	Have you been looking for work and ready for work in the last 4 weeks?	☐ Yes (Go to Q11)	☐ No

Ref	Question	Answer	☑
10	What was the **main** reason for not working or looking for work in the last 4 weeks?	Household & Family / Child Care Role	☐
		Seasonal Inactivity	☐
		Student	☐
		No Work Available	☐
		Too Old / Young	☐
		My Hearing Problem	☐
		Other	☐
11	How many jobs did you have in the last year?		**Number** ☐ **If 0: Skip To Part 4**
12	Please name **the three main jobs** in order of importance (Greatest income source first)	Over the last 12 **months**, how many months did you work on this job?	How many hours per week did you work in the **last month?**
	Job 1 Title:	☐	☐

	Job 2 Title:	☐	☐
	Job 3 Title:	☐	☐

Ref	Question	Answer	☑
13	Did you work relatively more or less than usual in the last month?	More than usual	☐
		Same as usual	☐
		Less than usual	☐
14	How were you paid for the main job? (Job 1)	Wages/Salary	☐
		Payment in Kind	☐
		Casual (hourly/daily)	☐
		Unpaid or Volunteer	☐
		Self-employed	☐
15	For whom did you work for in your main job?	Government	☐
		Non-Government Organisation	☐
		Private Business	☐
		Private Person/Household	☐
		Other (Specify)	☐

16	What is the **main activity** at the place of your main job?	Agriculture/Farming	☐
		Manufacturing/ Processing	☐
		Building & Construction	☐
		Transport	☐
		Shop/Selling/Vendor	☐
		Hospitality (Waiter/Chef/Housekeeper)	☐
		Education/Health	☐
		Other (Specify)	☐

Ref	Question	Answer	No ☑	Yes ☑
17	Are you entitled to any of the following?	Paid Sick Leave	☐	☐
		Paid Holiday	☐	☐
		Maternity/Paternity Leave	☐	☐
		Retirement Pension	☐	☐
		Social Security Benefits	☐	☐
		Health Insurance/ Free Medical Care	☐	☐

Part 04: Income

Ref	Statement	Answer ☑	
1	I'm now going to ask you some questions regarding you and your household's financial income.	☐ Yes: Proceed To Part 4: Q2	☐ Refused Go to Part 5

Ref	Question	Weekly Amount (Q)	Monthly Amount (Q)
2	What is your weekly / monthly income from your job?		
3	What is the total weekly/monthly income from other household members jobs?		
4	Does the household have any other sources of income? If so, how much? For Example: Do You/Your Household: ▪ Sell products, wash clothes or make food for others? ▪ Have a pension? ▪ Have financial support from your family ▪ Receive any remittances? ▪ Receive any interest on savings or on loans you have made?		
	Total Income Per Week / Month		
	Calculation	**X52**	**X12**
	Total Annual Household Income		

Part 05: Household Spending & Consumption

1. In the past 7 days, has any member of your household spent money on any of the following items?			How much did your household spend on each item?
Items	No ☑	Yes ☑	QUETZAL Q.
Tobacco, cigarettes, cigars	☐	☐	
Newspapers or magazines	☐	☐	
Lottery tickets	☐	☐	
Fares for public transport: busses, taxis, etc.	☐	☐	
Petrol, oil and car service	☐	☐	
Parking	☐	☐	
Charity	☐	☐	
Restaurant or Café Meals, Beverages & Snacks	☐	☐	
		Total: Week	

2. Over the past week has your household eaten the following food items?	Eaten		Value	Purchased	Gift	Payment
	Yes ☑	No ☑	Q.	☑	☑	☑
Vegetable Oils & Cooking Fat	☐	☐		☐	☐	☐
Butter or Margarine	☐	☐		☐	☐	☐
Milk (Liquid/Powder)	☐	☐		☐	☐	☐
Eggs	☐	☐		☐	☐	☐
Other Dairy Products Example: Yoghurt & Cheese	☐	☐		☐	☐	☐
Vegetables Example: Potato/Salad/Avocado	☐	☐		☐	☐	☐
Fresh Meat & Poultry	☐	☐		☐	☐	☐
Fresh Fish	☐	☐		☐	☐	☐
Fruit: Water Melon/Papaya	☐	☐		☐	☐	☐
Beans	☐	☐		☐	☐	☐
Rice	☐	☐		☐	☐	☐
Nuts	☐	☐		☐	☐	☐
Tortilla	☐	☐		☐	☐	☐
		Weekly Total				

3. Over the past month has your household eaten the following Food Items?	Eaten		Value	Purchased	Gift	Payment
	Yes ☑	No ☑	Q.	☑	☑	☑
Breakfast Cereal	☐	☐		☐	☐	☐
Flour / Grain	☐	☐		☐	☐	☐
Sugar	☐	☐		☐	☐	☐
Baby Formula	☐	☐		☐	☐	☐
Chocolate	☐	☐		☐	☐	☐
Canned Foods (fish, fruit)	☐	☐		☐	☐	☐
Soft Drinks	☐	☐		☐	☐	☐
Beer and Alcoholic Beverages	☐	☐		☐	☐	☐
Biscuits and Cakes	☐	☐		☐	☐	☐
Spices and Condiments	☐	☐		☐	☐	☐
Jam	☐	☐		☐	☐	☐
Tea	☐	☐		☐	☐	☐
Coffee	☐	☐		☐	☐	☐
Any Other Food Items Not Listed Specify:	☐	☐		☐	☐	☐
Monthly Total						

4. Over the past month has your household spent money on any of the following Items?	Spent		Value
	Yes ☑	No ☑	Q.
Personal care items (haircuts, cosmetics, shampoo, toothpaste)	☐	☐	
Clothing or shoes for adults	☐	☐	
Clothing or shoes for children (including school uniform)	☐	☐	
Material to make clothing, curtains and other items	☐	☐	
Telephone (service + calls + prepaid) Including Cell Phone	☐	☐	
Holidays & Excursions	☐	☐	
Jewellery, watches and other luxury goods	☐	☐	
Birthdays & Ceremonies (Weddings & Funerals)	☐	☐	
Membership Fees	☐	☐	
Monthly Total			

5. **Entertainment**: Over the **past month** has your **household** spent money on any of the following items?	Spent		Value
	Yes ☑	No ☑	Q.
Books & Stationary (Excluding Textbooks)	☐	☐	
Postal Expenses	☐	☐	
Entertainment/Leisure (Cinema, DVD Rentals, Music, Sporting Events)	☐	☐	
Internet & TV / Cable	☐	☐	
Sports / Hobby Equipment	☐	☐	
		Total	

6. **Healthcare Expenses**: Over the **past month** has your **household** spent money on any of the following?	Spent		Value
	Yes ☑	No ☑	Q.
Medical Insurance Fees	☐	☐	
Hospital/Clinic Costs: Dentists/Doctor/Nurse Fees	☐	☐	
Medical Supplies: Medicines, Bandages	☐	☐	
Natural / Complementary Therapy	☐	☐	
		Total	

7. **Household Expenses**: Over the **past month** has your **household** spent money on any of the following?	Spent		Value
	Yes ☑	No ☑	Q.
Household Cleaning (soap, washing powder)	☐	☐	
Kitchen Equipment (pots, pans, lamps, torches)	☐	☐	
Bedding Sheets, Blankets and Towels	☐	☐	
Furniture and Household Appliances	☐	☐	
Home Maintenance and Repairs	☐	☐	
Fuel (Firewood, Charcoal, Cooking Gas)	☐	☐	
All Other Household Expenses Specify:	☐	☐	
		Total	

8. Education Fees: Over the past month has your household spent money on the following?	Spent		Value
	Yes ☑	No ☑	Q.
School Fees and Tuition	☐	☐	
University Fees	☐	☐	
Other School Expenses (books, transport, meals at school)	☐	☐	
		Total	

9. Tax & Legal Fees: Over the past month has your household spent money on any of the following? (Prompt: An annual 1/12th Proportion)	Spent		Value
	Yes ☑	No ☑	Q.
Income Tax	☐	☐	
Land Tax/Land Rates	☐	☐	
Housing and property tax	☐	☐	
Legal or notary services	☐	☐	
		Total	

10. Insurance & Fees: Over the past month has your household spent money on any of the following?	Spent		Value
	Yes ☑	No ☑	Q.
Insurance (Car & Property)	☐	☐	
		Total	

11. Other Expenses: Over the past month has your household spent money on any other items or services? Please specify below.	Spent		Value
	Yes ☑	No ☑	Q.
Specify:	☐	☐	
Specify:	☐	☐	
		Total	

Total Monthly Expenditure (Q)	

Part 06: General Health (Show Card: Scale A)

Ref	Question	No ☑	Yes: Some Difficulty ☑	Yes: Lots of Difficulty ☑	Cannot Do At All ☑
1	Do you have difficulty seeing, even if wearing Glasses?	☐	☐	☐	☐
2	Do you have difficulty hearing, even if using a hearing aid?	☐	☐	☐	☐
3	Do you have difficulty walking or climbing steps?	☐	☐	☐	☐
4	Do you have difficulty remembering or concentrating?	☐	☐	☐	☐
5	Do you have difficulty (with self care such as) with washing all over or dressing?	☐	☐	☐	☐
6	Using your usual (customary) language, do you have difficulty communicating, for example, understanding or being understood?	☐	☐	☐	☐

Part 07: Mental Health (Show Card: Scale B)

Ref	Read Question: Over the last two weeks, how often have you been bothered by any of the following problems?	Not at all ☑	Several Days ☑	More than half the days ☑	Nearly every day ☑
1	Little interest or pleasure in doing things	☐	☐	☐	☐
2	Feeling down, depressed or hopeless	☐ Go To Part 08	☐	☐	☐
3	Trouble falling or staying asleep, or sleeping too much	☐	☐	☐	☐
4	Feeling tired or having little energy	☐	☐	☐	☐
5	Poor appetite or overeating	☐	☐	☐	☐
6	Feeling bad about yourself…or that you are a failure or have let yourself or family down?	☐	☐	☐	☐
7	Trouble concentrating on things, such as reading the newspaper or watching television?	☐	☐	☐	☐
8	Moving or speaking so slowly that other people could have noticed. Or the opposite, being so fidgety or restless that you have been moving around a lot more than usual?	☐	☐	☐	☐
9	Thoughts that you would be better off dead, or of hurting yourself	☐	☐	☐	☐
Ref	**Question**	Not difficult at all ☑	Somewhat difficult ☑	Very difficult ☑	Extremely difficult ☑
10	If you have experienced any of these problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	☐	☐	☐	☐

Part 08: Quality of Life (Show Card: Scales C-G)

Ref	Question	Very Poor ☑	Poor ☑	Neither Poor nor Good ☑	Good ☑	Very Good ☑
1	How would you rate your quality of life?	☐	☐	☐	☐	☐

Ref	Question	Very Dissatisfied ☑	Dissatisfied ☑	Neither satisfied nor Dissatisfied ☑	Satisfied ☑	Very Satisfied ☑
2	How satisfied are you with your health?	☐	☐	☐	☐	☐

Ref	The following questions ask about how much you have experienced certain things over the last four weeks?	Not at all ☑	A Little ☑	A Moderate Amount ☑	Very Much or Mostly ☑	An Extreme Amount /Completely ☑
3	To what extent do you feel that physical pain prevents you from doing what you need to do?	☐	☐	☐	☐	☐
4	How much do you need any medical treatment to function in your daily life?	☐	☐	☐	☐	☐
5	How much do you enjoy life?	☐	☐	☐	☐	☐
6	To what extent do you feel your life to be meaningful?	☐	☐	☐	☐	☐
7	How well are you able to concentrate?	☐	☐	☐	☐	☐
8	How safe do you feel in your daily life?	☐	☐	☐	☐	☐
9	How healthy is your physical environment?	☐	☐	☐	☐	☐
10	Do you have enough energy for everyday life?	☐	☐	☐	☐	☐
11	Are you able to accept your bodily appearance?	☐	☐	☐	☐	☐
12	Have you enough money to meet your needs?	☐	☐	☐	☐	☐

13	How available to you is the information that you need in your day-to-day life?	☐	☐	☐	☐	☐
14	To what extent do you have the opportunity for leisure activities?	☐	☐	☐	☐	☐
Ref	Question	Very Poor ☑	Poor ☑	Neither Poor nor Good ☑	Good ☑	Very Good ☑
15	How well are you able to physically move and get around?	☐	☐	☐	☐	☐
Ref	Question	Very Dissatisfied ☑	Dissatisfied ☑	Neither Satisfied nor Dissatisfied ☑	Satisfied ☑	Very Satisfied ☑
16	How satisfied are you with your sleep?	☐	☐	☐	☐	☐
17	How satisfied are you with your ability to perform your daily living activities?	☐	☐	☐	☐	☐
18	How satisfied are you with your capacity to work?	☐	☐	☐	☐	☐
19	How satisfied are you with yourself?	☐	☐	☐	☐	☐
20	How satisfied are you with your personal relationships?	☐	☐	☐	☐	☐
21	How satisfied are you with your close (intimate) relationships?	☐	☐	☐	☐	☐
22	How satisfied are you with the support you get from your friends?	☐	☐	☐	☐	☐
23	How satisfied are you with the conditions of your living place?	☐	☐	☐	☐	☐
24	How satisfied are you with your access to health services?	☐	☐	☐	☐	☐
25	How satisfied are you with transport?	☐	☐	☐	☐	☐
Ref	The following question refers to how often you have felt or experienced certain things in the last four weeks.	Never ☑	Seldom ☑	Quite Often ☑	Very Often ☑	Always ☑
26	How often do you have negative feelings such as blue moods, despair, anxiety or depression?	☐	☐	☐	☐	☐

Case Group Only: Proceed to Part 09: Hearing

Control Group Only: The Last Question

Ref	Control Last Question	Answer
CONLQ	Thank you for your help in answering these questions today. Do you have any final comments you wish to share?	

Part 09: Hearing

Ref	Question	Never ☑	One Day Per Week ☑	2-6 Days Per Week ☑	Everyday ☑
1	How many days per week do you wear your hearing aids?	☐	☐	☐	☐

Ref	Question	None ☑	Less than 1 Hour Per Day ☑	1-4 Hours Per Day ☑	4-8 Hours Per Day ☑	8-16 Hours Per Day ☑
2	On a daily basis, how often do you use your hearing aids?	☐	☐	☐	☐	☐

Ref	Question	Answer	☑
3	**If answered 'Everyday' AND '8-16 Hours' skip this question.** What is the **main reason** why you don't wear your hearing aids **all day, every day**. Tick **one** box only.	They are uncomfortable	☐
		They don't help my hearing	☐
		They are broken	☐
		They were lost or stolen	☐
		I only wear them when I go out	☐
		I don't need to communicate all of the time	☐
		I feel embarrassed wearing them	☐
		Other Reason: Please State:	☐

Part 9a: Hearing

Ref: SADL	Question (See Show Card H)	A Not a lot ☑	B A Little ☑	C Somewhat ☑	D Medium ☑	E Considerably ☑	F Greatly ☑	G Tremendously ☑
1	Compared to using no hearing aids at all, do your hearing aids help you understand the people you speak with most frequently?	☐	☐	☐	☐	☐	☐	☐
2	Are you frustrated when your hearing aids pick up sounds that keep you from hearing what you want to hear?	☐	☐	☐	☐	☐	☐	☐
3	Are you convinced that obtaining your hearing aids was in your best interest?	☐	☐	☐	☐	☐	☐	☐
4	Do you think people notice your hearing loss more when you wear your hearing aids?	☐	☐	☐	☐	☐	☐	☐
5	Do your hearing aids reduce the number of times you have to ask people to repeat?	☐	☐	☐	☐	☐	☐	☐
6	Do you think your hearing aids are worth the trouble?	☐	☐	☐	☐	☐	☐	☐
7	Are you bothered by an inability to get enough loudness from your hearing aids without feedback? (whistling)	☐	☐	☐	☐	☐	☐	☐
8	How content are you with the appearance of your hearing aids?	☐	☐	☐	☐	☐	☐	☐
9	Does wearing your hearing aids improve your self-confidence?	☐	☐	☐	☐	☐	☐	☐
10	How natural is the sound from your hearing aid's?	☐	☐	☐	☐	☐	☐	☐
11	How helpful are your hearing aids on the telephone? (with no amplifier on loudspeaker)	☐	☐	☐	☐	☐	☐	☐
12	How competent was the person who provided you with your hearing aids?	☐	☐	☐	☐	☐	☐	☐
13	Do you think wearing your hearing aids makes you seem less capable?	☐	☐	☐	☐	☐	☐	☐
14	Does the cost of your hearing aids seem reasonable to you?	☐	☐	☐	☐	☐	☐	☐
15	How pleased are you with the dependability (how often they need repair) of your hearing aids?	☐	☐	☐	☐	☐	☐	☐

Part 9b: Hearing

Ref: IOI-HA	Question	None ☑	Less than 1 Hour Per Day ☑	1-4 Hours Per Day ☑	4-8 Hours Per Day ☑	More Than 8 Hours Per Day ☑
1	Think about how much you have used your hearing aids over the past two weeks. On an average day, how many hours did you use the hearing aids?	☐	☐	☐	☐	☐
Ref: IOI-HA	Question	Helped Not At All	Helped slightly	Helped moderately	Helped quite a lot	Helped very much
2	Think about the situation where you most wanted to hear better before you got your hearing aids. Over the past two weeks, how much has your hearing aids helped in that specific situation?	☐	☐	☐	☐	☐
Ref: IOI-HA	Question	Very much difficulty	Quite a lot of difficulty	Moderate difficulty	Slight difficulty	No difficulty
3	Think again about the situation where you most wanted to hear better. When you use your hearing aids how much difficulty do you still have in that situation?	☐	☐	☐	☐	☐
Ref: IOI-HA	Question	Not At All Worth It	Slightly Worth It	Moderately Worth It	Quite a Lot Worth It	Very Much Worth It
4	Considering everything, do you think your hearing aid(s) are worth the trouble?	☐	☐	☐	☐	☐
Ref: IOI-HA	Question	Affected very much	Affected quite a lot	Affected moderately	Affected slightly	Affected not at all
5	Over the past two weeks, with using your hearing aids, how much have your hearing difficulties affected the things you can do?	☐	☐	☐	☐	☐

Ref: IOI-HA	Question	Bothered very much	Bothered quite a lot	Bothered moderately	Bothered slightly	Bothered not at all
6	Over the past two weeks, with using your hearing aids, how much do you think other people were bothered by your hearing difficulties?	☐	☐	☐	☐	☐
Ref: IOI-HA	**Question**	**Worse**	**No change**	**Slightly better**	**Quite a lot better**	**Very much better**
7	Considering everything, how much have your hearing aids changed your enjoyment of life?	☐	☐	☐	☐	☐

Part 9c: Hearing

Ref	Question: When you are using your hearing aids:	Yes ☑	Sometimes ☑	No ☑
1	Does a hearing problem cause you to use the phone less often than you would like?	☐	☐	☐
2	Does a hearing problem cause you to feel embarrassed when meeting new people?	☐	☐	☐
3	Does a hearing problem cause you to avoid groups of people?	☐	☐	☐
4	Does a hearing problem make you irritable?	☐	☐	☐
5	Does a hearing problem cause you to feel frustrated when talking to members of your family?	☐	☐	☐
6	Does a hearing problem cause you difficulty when attending a party?	☐	☐	☐
7	Does a hearing problem cause you difficulty hearing/understanding co-workers, clients, or customers?	☐	☐	☐
8	Do you feel handicapped by a hearing problem?	☐	☐	☐
9	Does a hearing problem cause you difficulty when visiting friends, relatives, or neighbours?	☐	☐	☐
10	Does a hearing problem cause you to feel frustrated when talking to co-workers, clients, or customers?	☐	☐	☐
11	Does a hearing problem cause you difficulty in the movies or theatre?	☐	☐	☐
12	Does a hearing problem cause you to be nervous?	☐	☐	☐
13	Does a hearing problem cause you to visit friends, relatives, or neighbours less often than you would like?	☐	☐	☐
14	Does a hearing problem cause you to have arguments with family members?	☐	☐	☐

Ref	Question: When you are using your hearing aids:	Yes ☑	Sometimes ☑	Never ☑
15	Does a hearing problem cause you difficulty when listening to TV or radio?	☐	☐	☐
16	Does a hearing problem cause you to go shopping less often than you would like?	☐	☐	☐
17	Does any problem or difficulty with your hearing upset you at all?	☐	☐	☐
18	Does a hearing problem cause you to want to be by yourself?	☐	☐	☐
19	Does a hearing problem cause you to talk to family members less often than you would like?	☐	☐	☐
20	Do you feel that any difficulty with your hearing limits or hampers your personal or social life?	☐	☐	☐
21	Does a hearing problem cause you difficulty when sitting at a table and eating a meal with relatives or friends?	☐	☐	☐
22	Does a hearing problem cause you to feel depressed?	☐	☐	☐
23	Does a hearing problem cause you to listen to TV or the radio less often than you would like?	☐	☐	☐
24	Does a hearing problem cause you to feel uncomfortable when talking to friends?	☐	☐	☐
25	Does a hearing problem cause you to feel left out when you are with a group of people?	☐	☐	☐
	Total			

Part 9d: Hearing

Ref	Hearing Aid Features (Show Scale D)	Very Dissatisfied ☑	Dissatisfied ☑	Neither Satisfied nor Dissatisfied ☑	Satisfied ☑	Very Satisfied ☑
1	Overall fit / comfort	☐	☐	☐	☐	☐
2	Visibility to others	☐	☐	☐	☐	☐
3	Ease of changing battery	☐	☐	☐	☐	☐
4	Battery life	☐	☐	☐	☐	☐
5	Access to battery supplies	☐	☐	☐	☐	☐
6	Ability to adjust volume*	☐	☐	☐	☐	☐

7	Access to repair and maintenance services	☐	☐	☐	☐	☐
8	Frequency of cleaning required	☐	☐	☐	☐	☐
9	Ability to tell the location and direction of sounds	☐	☐	☐	☐	☐
10	The sound of your own voice	☐	☐	☐	☐	☐
11	Comfort with loud sounds	☐	☐	☐	☐	☐
12	Overall, how satisfied are you with your hearing aid(s)?	☐	☐	☐	☐	☐

Part 9e: Hearing

Ref	Question	Answer	☑
1	In your experience, with using hearing aids what has been the most significant benefit? None ☐ **(Tick one box only)**	Communication with family & friends	☐
		Watching TV / Listening to music	☐
		Able to now work and earn money	☐
		Feeling safer and / or more confident	☐
		Going out and participating in social activities	☐
		Other: Please State:	☐

Part 9f: Hearing

Ref	Question: When you are using your hearing aids ... **Scale: 1 = Never - 10 = Always**	1-10 Response (Show Scale G)
1	Do you experience communication difficulties in situations, which involve speaking with one other person? For example: Home/Work/Social Situation	
2	Do you experience communication difficulties when watching television or listening to the radio?	
3	Do you experience communication difficulties in situations when conversing with a small group of several persons? For example: With friends or family, co-workers or over dinner	
4	Do you experience communication difficulties when you are in an unfavorable listening environment, such as at a noisy party, when there is background music, when riding on the bus or when someone whispers/talks from across the room?	

5	How often do you experience communication difficulties in a situation when you need or want to hear well? For example: Trying to hear instructions or information	
6	Do you feel that any difficulty with hearing negatively affects or hampers your personal or social life?	
7	Does any problem or difficulty with hearing worry, annoy or upset you?	
8	Do your family, friends or co-workers seem to be concerned, annoyed or suggest that you have a hearing problem?	
9	How often does hearing loss negatively affect your enjoyment of life?	
10	How often has your hearing problem potentially caused or contributed to a safety or security concern? Either at home or at work? Can you explain what happened?	
	Total Score	

Final Question Set:

Ref Number	Question	Answer
1	Thank you for your help in answering these questions today. Do you have any final comments you wish to share?	

Ref Number	Question	Answer ☑		
2	With your consent, I would now like to ask another member of your household a few questions about your hearing.	Consent Yes ☐ Q3 + Part 10	Unavailable ☐ End Interview	Refused ☐ End Interview

Ref Number	Question	Answer ☑	
3	What is this member's relationship to you?	Husband	☐
		Wife	☐
		Daughter	☐
		Son	☐
		Other: Specify	☐

Interviewer Notes & Extended Answers

End of Interview

Part 10: Significant Other Question Set

Ref	Question	None ☑	Less than 1 Hour Per Day ☑	1-4 Hours Per Day ☑	4-8 Hours Per Day ☑	8-16 Hours Per Day ☑
A	How often does he/she use their hearing aids?	☐	☐	☐	☐	☐

Ref Number	Question: With using their hearing aids ... Scale: 1 = Never - 10 = Always (Show Scale G)	1-10 Response
1	Does he/she experience communication difficulties in situations, which involve speaking with one other person? For example: At home, in work or during a social situation?	
2	Does he/she experience communication difficulties when watching television or listening to the radio?	
3	Does he/she experience communication difficulties in situations when conversing with a small group of several persons? For example: With friends or family, co-workers or over dinner	
4	Does he/she experience communication difficulties when they are in an unfavorable listening environment, such as at a noisy party, when there is background music, when riding on the bus or when someone whispers/talks from across the room?	
5	How often does he/she experience communication difficulties in a situation when they need or want to hear well? For example: Unable to hear instructions or information being provided	
6	Do you feel that any difficulty with hearing negatively affects or hampers his or her personal or social life?	
7	Do you feel that any problem of difficulty with hearing worries, annoys or upsets him/her?	
8	Do you or others seem to be concerned, annoyed or suggest that he/she has a hearing problem?	
9	How often does hearing loss negatively affect his/her enjoyment of life?	
10	Since using their hearing aids, how often has his/her hearing problem potentially caused or contributed to a safety or security concern? Either at home or at work? If so, can you explain what happened?	
	Total Score	

Appendix 7

In-Depth Interview Schedule & Guide

Research Project Aim & Objectives

The aim of this study is to assess the impact of hearing impairment and the provision of hearing aids on socio-economic status (poverty), mental health, quality of life and activity participation in Guatemala.

Within Guatemala and based on an adult population:

1. Compare socio-economic status, quality of life, mental health and functional activity participation between individuals with mild-severe hearing loss and age, sex-matched adults with normal hearing.
2. Evaluate the impact of hearing aid provision on socio-economic status, mental health, quality of life and functional activity participation.
3. Assess hearing aid usage
4. Explore the barriers and facilitators to uptake and usage of hearing aids.
5. Assess patient satisfaction with hearing aids.

Inclusion Criteria

☐ Case Participant

☐ Hearing Aid Fitted

☐ Post Intervention Questionnaire Complete

Introductory Check List

Personal Introductions	☐	Audio Recording	Yes ☐ No ☐
Research Purpose & Format Explained	☐	Interview Start Time	
Ethics Information Sheet Reviewed	☐	Interview Finish Time	
Consent Form Signed	☐	Duration	
Hearing Aid Wearing Frequency Data	☐	Frequency: ☐ Hours	☐ Daily ☐ Weekly

Interview Participant Details

Name (First, Family)	
Gender	Male ☐ Female ☐
Date of Birth	Day Month Year
Age	☐ Years
Hearing Impairment	Bilateral ☐ Unilateral ☐ Left/Right Ear ☐

Interview Details

Interviewer Name	
Translator	Yes ☐ No ☐
Interview Location	Home ☐ Public Area ☐ Other ☐ Specify:
Interview Address	
Observations	Wearing Hearing Aids? Yes ☐ No ☐ Third Party Presence? Yes ☐ No ☐ Background Noise? Yes ☐ No ☐ **General Comments**

Questions

Domain	Hearing Aid Impact	Asked
Question 1	Have the hearing aids made any difference to your life?	☐
Prompts	☐ Communication ☐ Ability to work & generate Income ☐ Social Activities ☐ Relationships	☐

Domain	Hearing Aid Impact	Asked
Question 2	Could you provide an example of where you feel that your hearing aids have helped you the most?	☐
Prompts	☐ Home ☐ Work ☐ Social Activities ☐ How did that make you feel? ☐ How did this impact on others?	☐

Domain	Hearing Aid Impact	Asked
Question 3	Is there anything that you dislike about wearing hearing aids? Can you provide an example?	☐
Prompts	☐ Do you ever experience negative attitudes or behaviours towards you? Can you explain your experience? ☐ Care & Maintenance? ☐ Sound Quality (Volume/Direction/Background Noise)	☐

Domain	Hearing Loss Impact	Asked
Question 4	On reflection, what would you say was the most challenging aspect of having a hearing impairment? Can you provide an example?	☐
Prompts	Something that happened at home, at work or involving a family member?	☐

Domain	Hearing Loss Impact	Asked
Question 5	How did your hearing impairment make you feel? Prompt: Some people report that their hearing loss made them feel sad or unhappy… how about you?	☐
Supplementary Questions	How did those feelings impact on you and your family, your home and work life? What difference have the hearing aids made to these feelings?	☐

Domain	Barriers & Facilitators to Usage	Asked
Question 6 & 7	(a) What do you think about the hearing test and hearing aid fitting process? (b) Would you recommend the service to others?	☐
Prompts	☐ Process Explanation? ☐ Did you receive guidance and support? ☐ Were all your questions answered? ☐ General Customer Service?	☐

Domain	Barriers & Facilitators to Usage	Asked
Question 8	Are your hearing aids reliable (always work) and comfortable to wear? Can you show me how you would replace the battery?	☐
Supplementary Questions	☐ Where do you store your hearing aids overnight? ☐ Where do you get replacement batteries? ☐ What happens if the aid stops working, what do you do?	☐

Domain	Open Dialogue	Asked
Question 9	☐ Is there anything else important about the topics that we have discussed which you would like to add? ☐ Would you like to ask me any questions?	☐
Prompts	☐ Your Experiences? ☐ Concerns? ☐ Practical Issues?	☐

Thank You: End of Interview